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Food and Drug Administration

Classification of Microbiology or Immunology Devices; Development of General Provisions; Proposed Rules

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

21 CFR Part 866

[Docket No. 78N-2113]

Classification of Microbiology or Immunology Devices; Development of General Provisions

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The agency is proposing general rules applicable to the classification of all microbiology or immunology devices. The Medical Device Amendments of 1976 require the Food and Drug Administration (FDA) to classify all medical devices intended for human use into three categories: class I, general controls; class II, performance standards; and class III, premarket approval. In the preamble to this proposal, FDA describes the development of the proposed regulations classifying individual microbiology or immunology devices, which are being published elsewhere in this issue of the **Federal Register**. The preamble also describes the activities of the Microbiology Device Classification Panel and the Immunology Device Classification Panel, FDA advisory committees that make recommendations to FDA concerning the classification of microbiology and immunology devices.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register**.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7550.

SUPPLEMENTARY INFORMATION:

Device Classification System

The Medical Device Amendments of 1976 (Pub. L. 94-295) (hereinafter called the amendments) establish a comprehensive system for the regulation of medical devices intended for human use. One provision of the amendments, section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c) establishes three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories are as follows: class I, general controls; class II, performance standards; and class III, premarket approval.

Most devices are not classified under section 513 of the act until after FDA has (1) received a recommendation from a device classification Panel (an FDA advisory committee); (2) published the Panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. These steps must precede the classification of any device that was in commercial distribution before May 28, 1976 (the date of enactment of the amendments) and that was not previously regarded by FDA as a new drug under section 505 of the act (21 U.S.C. 355). A device that is first offered for commercial distribution after May 28, 1976, and that is substantially equivalent to a device classified under this scheme, is classified in the same class as the device to which it is substantially equivalent.

A device that FDA previously regarded as a new drug, or a newly offered device that is not substantially equivalent to a device that was in commercial distribution before the amendments, is classified by statute into class III. These two types of devices are classified into class III without any FDA rulemaking proceedings. The agency determines whether new devices are substantially equivalent to previously offered devices by means of the premarket notification procedure in section 510(k) of the act (21 U.S.C. 360(k)) and Part 807 of the regulations (21 CFR Part 807).

Related Regulations

In the **Federal Register** of July 28, 1978 (43 FR 32988), the agency issued final regulations describing the procedures for classifying devices intended for human use. These regulations, which were proposed in the **Federal Register** of September 13, 1977 (42 FR 46028), supplement the agency's regulations in Part 14 (21 CFR Part 14) governing the use of advisory committees. The agency also issued interim device classification procedures in a notice published in the **Federal Register** of May 19, 1975 (40 FR 21848).

Microbiology and immunology devices are subject to labeling requirements in § 809.10 (21 CFR 809.10) for in vitro diagnostic products. As defined in § 809.3(a) (21 CFR 809.3(a)), in vitro diagnostic products are those reagents, instruments, and systems intended for use in the diagnosis of disease or in the determination of the state of health in order to cure, mitigate, treat, or prevent disease or its sequelae. These products are intended for use in the collection, preparation, and examination of specimens taken from the human body. Before the enactment of the amendments, FDA regarded in vitro diagnostic products as drugs or devices, or as combinations of drugs and devices. Since the enactment of the amendments, with their expanded definition of "device" in section 201(h) of the act (21 U.S.C. 321(h)), FDA regards in vitro diagnostic products as devices.

Certain in vitro diagnostic products are also biological products subject to section 351 of the Public Health Service Act (42 U.S.C. 262). However, FDA has not yet obtained the Panels' recommendations concerning the classification of microbiology and immunology devices that are licensed biological products. In the future, FDA will obtain the Panels' recommendations concerning the classification of these products and publish these recommendations and proposed regulations in the **Federal Register**. FDA will also publish a separate notice concerning the regulation of leukocyte typing serum, a product that is both a device and a licensed biological product and that is a valuable reagent for identifying suitable donors for organ transplants and platelet and leukocyte transfusions.

In addition, two devices that contain antibiotics (antimicrobial susceptibility test discs and antimicrobial susceptibility test powders) are subject to premarket approval regulations for antibiotics under section 507 of the act (21 U.S.C. 357). Section 520(1)(4) of the act (21 U.S.C. 360j(1)(4)) provides that if a class II device was subject to the requirements of section 507 on May 28, 1976 (the date of enactment of the amendments), these requirements shall continue to apply to the device until the effective date of a performance standard applicable to the device under section 514 of the act. Thus, devices that were then subject to the requirements of section 507 of the act continue to be subject to those requirements until the effective date of a performance standard for these devices.

Activities of Panels

Anticipating enactment of the amendments, FDA established several advisory committees to make preliminary recommendations on device classification. The Microbiology Device Classification Panel and the Immunology Device Classification Panel were originally chartered on April 9,

1972, as the Microbiology and the Immunology Subcommittees of the Diagnostics Products Advisory Committee.

On August 10, 1976, the Subcommittees were rechartered as the Microbiology Device Classification Panel and the Immunology Device Classification Panel to reflect their new responsibilities under the amendments. The agency directed each Panel to reconsider its preamendments classification recommendations in light of the new requirements. In 1976 and 1977, the Panels reviewed all devices that FDA had referred to it to make certain that their recommendations were in accord with the amendments. On April 28, 1978, the Panels were again rechartered and became sections of the Immunology and Microbiology Devices Panel.

Throughout the Panel's deliberations, interested persons were given an opportunity to present their views, data, and other information concerning the classification of microbiology and immunology devices. The Panels also invited experts to testify and sought information on many devices from the published literature.

The Panels submitted to FDA preliminary reports of their recommendations. The reports included rosters of current and former Panel members and consultants and listed all meeting dates. The agency placed copies of the report in the office of the Hearing Clerk (HFA–305), Food and Drug Administration, and announced their availability to the public by notice published in the **Federal Register** of November 29, 1977 (42 FR 60792). Also available in the office of the Hearing Clerk are summary minutes from all Panel meetings, verbatim transcripts of meetings held after May 28, 1976 (the date of enactment of the amendments), and all references cited in individual microbiology and immunology device proposed classification regulations. Interested persons may review these documents in the office of the Hearing Clerk (address above).

Relationship Between the Device Names in the Device Registration and Listing Codes and the Device Names in Classification Regulations

The agency is aware that manufacturers have become accustomed to identifying a device by its registration and listing classification name and three letter code for purposes of device listing. However, changes in the names and identifications of generic types of devices in the classification regulations are still being made in all panels for which final regulations have not been published. The agency believes that use of the present device registration and listing classification names in the regulations would complicate the agency's publication of the classification regulations unnecessarily. To aid a manufacturer in matching its device with the proper classification regulation, FDA has prepared an index of names of generic types of medical devices used in classification regulations. The index shows the device regulation and listing product code for each device reviewed by a classification panel and the corresponding name of the generic type of device and classification panel in which the device classification will be published in the **Federal Register.** The agency announced the availability of this index in the **Federal Register** of March 6, 1979 (44 FR 12269). If necessary, this index will be updated and the availability of the revised index will be reannounced in the **Federal Register.** FDA believes that because this index is available, it is unnecessary to include or cross-reference the present device registration and listing name and product code in each device in the classification regulations. In the future, following publication of most of the device classification regulations, the agency will revise and reissue the device regulation and listing product code so the device names to be used for registration and listing correspond to the device names in the final device classification regulations.

List of Microbiology and Immunology Devices

In 1972 FDA surveyed device manufacturers to identify the devices for which classification regulations would be needed. Following this survey, FDA developed a list of microbiology and immunology devices. The Panels supplemented the list utilizing their members' knowledge of microbiology and immunology devices in use. Devices that were solely for experimental or investigational use or that were not generally available were not included.

FDA is proposing to establish a new Part 866 in Title 21 of the Code of Federal Regulations. Part 866 will consist of sections identifying each microbiology or immunology device with a brief narrative description and stating the classification of that device. A list of the microbiology and immunology devices appears elsewhere in this preamble.

Individual Microbiology and Immunology Device Classification Regulations

Elsewhere in this issue of the **Federal Register,** FDA is issuing 88 individual proposed regulations to classify each microbiology device. The agency is proposing to classify 63 microbiology devices into class I (general controls) and 25 microbiology devices into class II (performance standards). The agency is also issuing 73 individual proposed regulations to classify each immunology device. The agency is proposing to classify 35 immunology devices into class I (general controls) and 38 immunology devices into class II (performance standards). The agency is not proposing to classify any microbiology or immunology devices into class III (premarket approval). FDA also is publishing the recommendations of the Panels regarding these devices as required by section 513(c)(2) and (d)(1) of the act (21 U.S.C. 360c(c)(2) and (d)(1)).

Published Panel Recommendations

Each published Panel recommendation concerning a microbiology and immunology device includes the information described below.

1. *Identification.* Both the Panel recommendation and proposed FDA classification regulation include a brief narrative identification of the device. The identification statement is necessarily broad because it applies to a category or type of device rather than to a specific device. As explained in proposed § 864.1, any manufacturer of a newly offered device that files a premarket notification submission under section 510(k) of the act (21 U.S.C. 360(k)) and Part 807 of the regulations (21 CFR Part 807) cannot show merely that the device is accurately described by the section title and identification provisions of a classification regulation. Although a new device may be described accurately by the title and identification in a classification regulation, it is nevertheless in class III under section 513(f) of the act if it is not substantially equivalent to a preamendments device (or to a postamendments device that has already been reclassified from class III into class I or class II). It is not practical for FDA to publish an identification of each type of device that is so detailed as to anticipate every product feature that may be relevant in determining whether a new device is substantially equivalent to previous devices classified by the regulation. The agency believes that this problem was recognized in, and addressed by, the premarket notification procedures in section 510(k) of the act. Accordingly, any manufacturer who submits a premarket notification submission should state why the manufacturer believes the device is

substantially equivalent to other devices in commercial distribution, as required by § 807.87 (21 CFR 807.87), and whether the device is described in a classification regulation.

2. *Recommended classification.* Each Panel's recommendation describes whether the device is recommended for classification into class I (general controls) or class II (performance standards).

For each device recommended for classification into class I, the Panel considered whether the device should be exempt from any requirements under certain sections of the act: section 510 (21 U.S.C. 360, registration), section 519 (21 U.S.C. 360i, records and reports), and section 520(f) (21 U.S.C. 360j(f), good manufacturing practice requirements). Although the Panels did not recommend that any device be exempted at this time from section 519 of the act, the Microbiology Device Classification Panel did recommend that the manufacturers of six class I devices be exempted from the good manufacturing practice regulation in the manufacture of these devices. The Immunology Device Classification Panel recommended that manufacturers of two class I devices be exempted from the premarket notification requirements of section 510(k) of the act and Part 807 of the regulations (21 CFR Part 807). The agency's policy concerning these exemption recommendations is discussed below in the section of this proposal concerning "Exemptions for Class I Devices."

A Panel's recommendation that a device be classified into class II includes the Panel's recommended priority ("high," "medium," or "low") for establishing a performance standard for the device. As explained below in the section of this notice concerning "Priorities for Class II Devices," however, the agency is not proposing the establishment of FDA priorities at this time.

3. *Summary of reasons for recommendation.* The summary of reasons for the Panel's recommendation explains why the Panel believes that a particular device meets the statutory criteria for classification into class I or class II.

Except in those instances in which FDA's classification proposal differs from the Panel's recommendation, FDA is adopting the Panel's summary of reasons as the agency's statement of the reasons for issuing the regulations, as required by section 517(f) of the act (21 U.S.C. 360g(f)).

The Panels and FDA have not identified any device subject to these proposals as implants or as life-supporting or life-sustaining devices.

4. *Summary of data on which the recommendation is based.* In many cases, the Panels based their recommendations on the Panel members' personal knowledge of, and clinical experience with, the devices under review. The Panels particularly relied upon clinical experience and judgment when considering a simple device that had been used extensively and was accepted widely before the amendments were enacted. The legislative history of the amendments makes clear that the term "data" has a special meaning in section 513(c)(2)(A) of the act, which requires that a panel's recommendation summarize the data upon which a recommendation is based. As used in that section, "data" refers not only to the results of scientific experiments, but also to less formal evidence, other scientific information or judgments of experts (House Committee on Interstate and Foreign Commerce, Medical Device Amendments of 1976, H.R. Rept. No. 94–853, 94th Congress, 2d Session 40 (1976)). The agency has determined that clinical experience and judgment is valid scientific evidence for classifying certain devices.

In many cases, FDA sought more data and information concerning the classification of a device than were cited by the Panels. References to these data and information are found in the "Proposed Classification" section of the preambles to individual microbiology and immunology device regulations. FDA is adopting, as the agency's statement of the basis for issuing the regulation under section 517(f) of the act, the Panel's summary of the data on which a recommendation to classify a device is based, together with any additional data and information cited in the preamble to the proposed classification regulation.

5. *Risks to health.* In identifying the risks to health presented by microbiology or immunology devices, the Panels recognized that few devices are completely free of risk. The Panels listed the risks they considered most significant, especially those that are unique to the individual device. In some cases, FDA has identified additional risks to health presented by a device. These additional risks are set out in the section of the preamble concerning the "Proposed Classification" of a particular device.

Because the classification recommendations and FDA regulations do not identify all risks to health presented by microbiology and immunology devices, future regulations establishing performance standards under section 514 of the act (21 U.S.C. 360d) or requiring premarket approval under section 515(b) of the act (21 U.S.C. 360e(b)) may identify additional risks to health to be addressed by FDA requirements.

Proposed Classification

Each proposed regulation to classify a microbiology or immunology device states whether FDA agrees with the Panel's recommendation, describes the agency's proposed classification of the device, and proposes a new section in Part 866 in which the device classification will be codified.

FDA cautions that the final classification of a device may differ from the proposal. Factors that may cause such a change include comments, the agency's reconsideration of existing data and information, and the agency's consideration of new data and information.

Priorities for Class II Devices

For a device that a Panel recommends be classified into class II, section 513(c)(2)(A) of the act requires that the Panel's recommendation include, to the extent practicable, a recommendation for the assignment of a priority for application to the device of a performance standard or premarket approval requirements. In developing its advice concerning priorities ("high," "medium," or "low") of devices recommended for classification into class II, the Panels compared the devices with other microbiology or immunology devices, based on information available to the Panel members concerning the relative importance of use of the device and the relative risks presented by the device. The Panels recommended assignment of a "high priority" only to those class II devices that the Panels believed should receive the agency's immediate attention.

FDA is not proposing at this time to establish priorities for development of performance standards for all class II devices. Section 513(d)(3) of the act authorizes, but does not require, establishment of these priorities. In the **Federal Register** of February 1, 1980 (45 FR 7493), FDA published a notice identifying which class II microbiology and immunology devices the agency found to warrant a high priority for the development of performance standards. At a later date, the agency will establish priorities for the development of standards for the remaining class II devices. All priorities established by the agency are based on the classification Panels' recommendations, availability resources, and other relevant factors.

The agency's priorities will be reflected in the agency's annual budget request and other publicly available documents and may be published in the **Federal Register.**

Exemptions for Class I Devices

Section 513 of the Federal Food, Drug, and Cosmetic Act (the act) provides that FDA may exempt a device recommended for classification into class I from a requirement under the following sections of the act: section 510 (21 U.S.C. 360, registration); section 519 (21 U.S.C. 360i, records and reports); and section 520(f) (21 U.S.C. 360j(f), good manufacturing practices).

Under section 510 of the act, a person "engaged in the manufacture, preparation, propagation, compounding or processing of * * * a device or devices" shall register with FDA (section 510(b) through (i)), file a list of devices (section 510(j)), and notify FDA at least 90 days before beginning commercial distribution of a device (section 510(k)). (See 21 CFR Part 807.) Section 510(g)(4) authorizes the agency to exempt a device from section 510 if it finds that compliance with that section is not necessary for the protection of the public health. In § 807.65 (21 CFR 807.65), FDA has exempted certain classes of persons from section 510. Several device classification panels have recommended that manufacturers of certain class I devices also be exempted from all or some of the requirements of section 510. The agency has determined that protection of the public health requires that manufacturers of medical devices, other than those already exempt under § 807.65, register and list their products with FDA to ensure that the agency can identify these manufacturers and their products and conduct necessary inspections.

The agency has determined, however, for certain devices, that it is not necessary for the protection of the public health that FDA receive premarket notification submissions. Thus, the agency is proposing to exempt certain devices from Subpart E of Part 807 of the regulations, which implements section 510(k). The agency does not, at this time, anticipate that premarket approval will be required for these devices. The agency believes that the semiannual updating of device listing under section 510(j)(2) will provide FDA with adequate notice of new products within these generic types of devices.

Section 519 of the act authorizes FDA to issue regulations requiring device manufacturers, importers, and distributors to establish and maintain such records, make such reports, and provide such information as the agency may reasonably require to assure that devices are not adulterated or misbranded and to otherwise assure their safety and effectiveness. The records and reports requirements in several of FDA's present device regulations are authorized, wholly or in part, by section 519. The most extensive of these requirements are found in the device good manufacturing practice (GMP) regulation (21 CFR Part 820). In the future, FDA will publish other regulations under section 519, including regulations requiring reports to FDA of experience with medical devices. Until these regulations are issued, FDA believes that it cannot properly grant exemptions from them. In the future, whenever the agency proposes device regulations that include records and reports requirements, interested persons may submit comments requesting that certain classes of manufacturers or other persons be exempted from the requirements, and FDA will grant exemptions that are appropriate.

The only type of exemption from records and reports requirements that FDA is proposing now, in device classification regulations, is an exemption of certain manufacturers from most requirements of the device GMP regulation. As explained below, the exemption will not extend to two device GMP records requirements.

The device GMP regulation was published in final form in the **Federal Register** of July 21, 1978 (43 FR 31508). At the time of the Panel's recommendations, the GMP regulation had not yet been promulgated, and the agency had not yet developed criteria for exempting a class I device from GMP requirements. The agency has now decided that, if any of the following criteria is met, FDA will consider exempting from the GMP regulation a class I device that is not labeled or otherwise represented as sterile. the agency will not, however, exempt a device from § 820.180, with respect to general requirements concerning records, or § 820.198, with respect to complaint files. The criteria are:

1. FDA has determined, based on adequate information about current practices in the manufacture of the device and about user experience with the device, that application of the GMP regulation is unlikely to improve the safety and effectiveness of the device.

2. FDA has determined that all possible defects relating to the safety and effectiveness of the device are readily detectable before use, either through visual examination by the user or routine testing before use, e.g., testing a clinical laboratory reagent with positive and negative controls.

3. FDA has determined that any defect in the device that is not readily detectable will not result in a device failure that could have an adverse effect on the patient or other user.

FDA has determined that no device that is labeled or otherwise represented as sterile will be exempted from the device GMP regulation. Such a device must be subject to the entire GMP regulation to ensure that manufacturers reduce adequately the bioburden (number of microorganisms) on the device and its components during the manufacturing process. This reduction is accomplished through adherence to a comprehensive quality assurance program as is required by the GMP regulation, with adequate environmental controls, trained personnel, appropriate maintenance and calibration of sterilization equipment, recordkeeping concerning lot sterility, strict packaging and labeling controls, and other quality assurance measures.

The agency also has determined that no exemption from the device GMP regulation will extend to § 820.180, with respect to general requirements concerning records, or § 820.198, with respect to complaint files. The agency believes that granting exemptions from these sections would not be in the public interest, and that compliance with these sections is not unduly burdensome for device manufacturers. To ensure that device manufacturers have adequate systems for complaint investigation and followup, all manufacturers are required to comply with the complaint file requirements of § 820.198. All device manufacturers also are required to comply with the general requirements concerning records in § 820.180 to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate.

In general, FDA has not initiated proposals to exempt manufacturers of class I devices from requirements under section 510, 519, or 520(f), but has acted on the basis of exemption recommendations of the device classification panels. Manufacturers and other interested persons may submit comments on the appropriateness of exemptions of manufacturers of class I devices that are not the subject of panel exemption recommendations. FDA will consider granting exemptions from the requirement of premarket notification and from the GMP regulation (other than

§§ 820.180 and 820.198) according to the policies and criteria discussed above. Comments requesting additional exemptions should be supported by information showing that the exemption of manufacturers of a device from the premarket notification requirement or the GMP regulation (other than §§ 820.180 and 820.198), or both, is consistent with the policies and criteria discussed above.

Guidelines for Preparing Petitions Requesting Exemption or Variance From the Device GMP Regulation for Devices Classified into Either Class I or Class II

FDA has prepared guidelines on the procedures that should be followed by persons who wish to submit petitions for exemption or variance from the device GMP regulation. These petitions may be submitted in accordance with provisions of section 520(f)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)(2)). The agency announced the availability of the guidelines in a notice published in the **Federal Register** of Friday, January 18, 1980 (45 FR 3671).

List of Microbiology and Immunology Devices

The following is a list of microbiology and immunology devices that shows the section in the Code of Federal Regulations under which the regulation classifying the device will be codified, the docket number of the proposed classification regulation, and the proposed classification of each device.

Section	Device	Docket No.	Class
	Subpart B—Diagnotic Devices		
866.1620	Antimicrobial susceptibility test disc	78N-2114	II
866.1640	Antimicrobial susceptibility test powder	78N-2115	II
866.1700	Culture medium for antimicrobial susceptibility tests	78N-2117	II
	Subpart C—Microbiology Devices		
866.2050	Staphylococcal typing bacteriophage	78N-2118	I
866.2120	Anaerobic chamber	78N-2119	I
866.2160	Coagulase plasma	78N-2121	II
866.2170	Automated colony counter	78N-2122	I
866.2180	Manual colony counter	78N-2123	I
866.2300	Multipurpose culture medium	78N-2124	I
866.2320	Differential culture medium	78N-2125	I
866.2330	Enriched culture medium	78N-2126	I
866.2350	Microbiological assay culture medium	78N-2127	I
866.2360	Selective culture medium	78N-2128	I
866.2390	Transport culture medium	78N-2129	I
866.2410	Culture medium for pathogenic *Neisseria* spp.	78N-2130	II
866.2440	Automated medium dispensing and stacking device	78N-2131	I
866.2450	Supplement for culture media	78N-2132	I
866.2480	Quality control kit for culture media	78N-2133	I
866.2500	Microtiter diluting and dispensing device	78N-2134	I
866.2540	Microbiological Incubator	78N-2135	I
866.2560	Microbial growth monitor	78N-2136	I
866.2580	Gas-generating device	78N-2137	I
866.2600	Wood's fluorescent lamp	78N-2138	I
866.2660	Microorganism differentiation and identification device	78N-2139	I
866.2850	Automated zone reader	78N-2140	I
866.2900	Specimen collection and transport device	78N-2141	I
	Subpart D—Serological Reagents		
866.3010	*Acinetobacter calcoaceticus* serological reagents	78N-2282	I
866.3020	Adenovirus serological reagents	78N-2142	I
866.3935	*Arizona* spp. serological reagents	78N-2143	I
866.3040	*Aspergillus* spp. serological reagents	78N-2144	I
866.3060	*Blastomyces dermatitidis* serological reagents	78N-2145	II
866.3065	*Bordetella* spp. serological reagents	78N-2146	I
866.3085	*Brucella* spp. serological reagents	78N-2147	II
866.3110	*Campylobacter* fetus serological reagents	78N-2149	I
866.3120	Chlamydia serological reagents	78N-2150	I
866.3125	*Citrobacter* spp. serological reagents	78N-2151	I
866.3135	*Coccidioides immitis* serological reagents	78N-2152	II
866.3140	*Corynebacterium* spp. serological reagents	78N-2153	I
866.3145	Coxsackievirus serological reagents	78N-2154	I
866.3165	*Cryptococcus neoformans* serological reagents	78N-2156	II
866.3175	Cytomegalovirus serological reagents	78N-2157	I
866.3200	*Echinococcus* spp. serological reagents	78N-2158	I
866.3205	Echovirus serological reagents	78N-2159	I
866.3220	*Entamoeba histolytica* serological reagents	78N-2160	II
866.3235	Epstein-Barr virus serological reagents	78N-2162	I

Section	Device	Docket No.	Class
	Subpart D—Serological Reagents—Continued		
866.3240	Equine encephalomyelitis virus serological reagents	78N-2163	I
866.3250	*Erysipelothrix rhusiopathiae* serological reagents	78N-2164	I
866.3255	*Escherichia coli* serological reagents	78N-2165	I
866.3270	*Flavobacterium* spp. serological reagents	78N-2166	I
866.3280	*Francisella tularensis* serological reagents	78N-2167	II
866.3300	*Haemophilus* spp. serological reagents	78N-2169	I
866.3305	Herpes simplex virus serological reagents	78N-2170	II
866.3320	*Histoplasma capsulatum* serological reagents	78N-2173	II
866.3330	Influenza virus serological reagents	78N-2174	I
866.3340	*Klebsiella* spp. serological reagents	78N-2175	I
866.3350	*Leptospira* spp. serological reagents	78N-2176	II
866.3355	*Listeria* spp. serological reagents	78N-2177	I
866.3360	Lymphocytic choriomeningitis virus serological reagents	78N-2178	I
866.3370	*Mycobacterium tuberculosis* immunofluorescent reagents	78N-2179	I
866.3375	*Mycoplasma* spp. serological reagents	78N-2180	I
866.3380	Mumps virus serological reagents	78N-2181	I
866.3390	*Neisseria* spp. direct serological test reagents	78N-2182	II
866.3400	Parainfluenza virus serological reagents	78N-2183	I
866.3405	Poliovirus serological reagents	78N-2184	I
866.3410	*Proteus* spp. (Weil-Felix) serological reagents	78N-2185	I
866.3415	*Psuedomonas* spp. serological reagents	78N-2186	II
866.3460	Rabiesvirus immunofluorescent reagents	78N-2187	II
866.3470	Reovirus serological reagents	78N-2188	I
866.3480	Respiratory syncytial virus serological reagents	78N-2189	I
866.3490	Rhinovirus serological reagents	78N-2190	I
866.3500	Rickettsia serological reagents	78N-2191	I
866.3510	Rubella virus serological reagents	78N-2192	II
866.3520	Rubeola (measles) virus serological reagents	78N-2193	I
866.3550	*Salmonella* spp. serological reagents	78N-2194	II
866.3600	*Schistosoma* spp. serological reagents	78N-2197	I
866.3630	*Serratia* spp. serological reagents	78N-2198	I
866.3660	*Shigella* spp. serological reagents	78N-2199	II
866.3680	*Sporothrix schenckii* serological reagents	78N-2200	I
866.3700	*Staphylococcus* aureus serological reagents	78N-2201	I
866.3720	*Streptococcus* spp. Exoenzyme reagents	78N-2202	II
866.3740	*Streptococcus* spp. serological reagents	78N-2203	I
866.3780	*Toxoplasma gondii* serological reagents	78N-2204	II
866.3820	*Treponema pallidum* nontreponemal test reagents	78N-2206	II
866.3830	*Treponema pallidum* treponemal test reagents	78N-2207	II
866.3850	*Trichinella spiralis* serological reagents	78N-2208	I
866.3870	*Trypanosoma* spp. serological reagents	78N-2209	I
866.3900	Varicella-Zoster serological reagents	78N-2210	I
866.3930	*Vibrio cholerae* serological reagents	78N-2211	II
	Subpart E—Immunology Laboratory Equipment and Reagents		
866.4100	Complement reagents	78N-2212	I
866.4500	Immunoelectrophoresis equipment	78N-2213	I
866.4520	Immunofluorometer equipment (includes U.V. immunologic test system).	78N-2214	I
866.4540	Immunonephelometer equipment (includes immunologic test system).	78N-2215	I
866.4600	Ouchterlony agar plate	78N-2216	I
866.4800	Radial immunodiffusion plate	78N-2217	I
866.4830	Rocket immunoelectrophoresis equipment	78N-2218	I
866.4900	Support gels	78N-2219	I
	Subpart F—Immunological Test Systems		
866.5040	Albumin immunological test system	78N-2220	II
866.5060	Prealbumin immunological test system	78N-2221	I
866.5065	Human allotypic marker immunological test system	78N-2222	I
866.5080	Alpha-1-antichymotrypsin immunological test system	78N-2223	II
866.5090	Antimitochondrial antibody immunological test system	78N-2224	II
866.5100	Antinuclear antibody immunological test system	78N-2225	II
866.5110	Antiparietal antibody immunological test system	78N-2226	II
866.5120	Antismooth muscle antibody immunological test system	78N-2227	II
866.5130	Alpha-1-antitrypsin immunological test system	78N-2228	II
866.5150	Bence-Jones proteins immunological test system	78N-2229	II
866.5160	Beta globulin immunological test system	78N-2284	I
866.5170	Breast milk immunological test system	78N-2230	I
866.5200	Carbonic anhydrase B and C immunological test system	78N-2231	I
866.5210	Ceruloplasmin immunological test system	78N-2232	II
866.5220	Cohn fraction II immunological test system	78N-2233	I
866.5230	Colostrum immunological test system	78N-2234	I
866.5240	Complement components immunological test system	78N-2235	II
866.5250	Complement C_1 inhibitor (inactivator) immunological test system.	78N-2236	II
866.5260	Complement C_{3b} inactivator immunological test system	78N-2237	II
866.5270	C-reactive protein immunological test system	78N-2238	II
866.5320	Properdin factor B immunological test system	78N-2239	II
866.5330	Factor XIII, A, S, immunological test system	78N-2240	I
866.5340	Ferritin immunological test system	78N-2241	II

Section	Device	Docket No.	Class
	Subpart F—Immunological Test Systems—Continued		
866.5350	Fibrinopeptide A immunological test system	78N-2242	II
866.5360	Cohn fraction IV immunological test system	78N-2243	I
866.5370	Cohn fraction V immunological test system	78N-2244	I
866.5380	Free secretory component immunological test system	78N-2245	II
866.5400	Alpha globulin immunological test system	78N-2246	I
866.5420	Alpha-1-glycoproteins immunological test system	78N-2247	I
866.5425	Alpha-2-glycoproteins immunological test system	78N-2248	I
866.5430	Beta-2-glycoprotein I immunological test system	78N-2249	I
866.5440	Beta-2-glycoprotein III immunological test system	78N-2250	I
866.5460	Haptoglobin immunological test system	78N-2251	II
866.5470	Hemoglobin immunological test system	78N-2252	II
866.5480	Hemolytic immunological test system	78N-2253	II
866.5490	Hemopexin immunological test system	78N-2254	II
866.5500	Hypersensitivity pneumonitis immunological test system	78N-2255	II
866.5510	Immunoglobulins A, G, M, D, and E immunological test system.	78N-2256	II
866.5520	Immunoglobulin G (Fab fragment specific) immunological test system.	78N-2257	II
866.5530	Immunoglobulin G (Fc fragment specific) immunological test system.	78N-2258	II
866.5540	Immunoglobulin G (Fd fragment specific) immunological test system.	78N-2283	I
866.5550	Immunoglobulin (light chain specific) immunological test system.	78N-2259	II
866.5560	Lactic dehydrogenase immunological test system	78N-2260	I
866.5570	Lactoferrin immunological test system	78N-2261	I
866.5580	Alpha-1-lipoprotein immunological test system	78N-2262	II
866.5590	Lipoprotein X immunological test system	78N-2263	I
866.5600	Low-density lipoprotein immunological test system	78N-2264	II
866.5620	Alpha-2-macroglobulin immunological test system	78N-2265	II
866.5630	Beta-2-microglobulin immunological test system	78N-2266	II
866.5640	Infectious mononucleosis immunological test system	78N-2267	II
866.5660	Multiple autoantibodies immunological test system	78N-2268	II
866.5680	Myoglobin immunological test system	78N-2269	II
866.5700	Whole human plasma or serum immunological test system	78N-2270	I
866.5715	Plasminogen immunological test system	78N-2271	I
866.5735	Prothrombin immunological test system	78N-2272	I
866.5750	Radioallergosorbent (RAST) immunological test system	78N-2273	II
866.5765	Retinol-binding protein immunological test system	78N-2274	I
866.5775	Rheumatoid factor immunological test system	78N-2275	II
866.5800	Seminal fluid (sperm) immunological test system	78N-2276	I
866.5820	Systemic lupus erythematosus immunological test system	78N-2277	II
866.5860	Total spinal fluid immunological test system	78N-2278	I
866.5870	Thyroid autoantibody immunological test system	78N-2279	II
866.5880	Transferrin immunological test system	78N-2280	II
866.5890	Inter-alpha tryspan inhibitor immunological test system	78N-2281	I

Devices Considered by two or More Panels

Many devices were reviewed by two or more device classification Panels. For these devices, FDA will publish each Panel's recommendations and a single proposed classification regulation. Several of the devices subject to proposals elsewhere in this issue of the **Federal Register** were reviewed by both the Microbiology Device Classification Panel and the Immunology Device Classification Panel. The following devices were considered by the Microbiology Device Classification Panel or the Immunology Device Classification Panel and by other Panels:

1. The Clinical Chemistry Device Classification Panel recommended that measurement of Bence-Jones proteins by immunochemical methods be classified into class II. The Immunology Device Classification Panel recommended that test systems for measurement of Bence-Jones proteins antigen, antiserum, control be classified into class II. FDA has determined that these devices are essentially the same. Therefore, the agency is proposing a single regulation classifying Bence-Jones proteins immunological test systems into class II and is publishing the two Panels' recommendation in a proposal appearing elsewhere in this issue of the **Federal Register.**

2. The Clinical Chemistry Device Classification Panel recommended that immunochemical methods for measurement of ceruloplasmin by indirect copper assay and phenylenediamine/EDTA (spectrophotometric) quantitative methods to measure copper be classified into class II. The Immunology Device Classification Panel recommended that ceruloplasmin, antigen, antiserum, control; ceruloplasmin, FITC, antigen, antiserum, control; and cruloplasmin rhodamine, antigen, antiserum, control be classified into class II. FDA has determined that these devices are essentially the same. Therefore, the agency is proposing a single regulation classifying immunological test systems for the measurement of ceruloplasmin into class II and is publishing the two Panels' recommendation in a proposal appearing elsewhere in this issue of the **Federal Register.**

3. The Clinical Chemistry Device Classification Panel recommended that test systems for immunochemical measurement of thyroglobulin autoantibody be classified into class II. The Immunnology Device Classification Panel recommended that thyroglobulin, antigen, antiserum, control; thyroglobulin, FITC, antigen, antiserum, control; and thyroglobulin, rhodamine, antigen, antiserum, control be classified into class II. FDA has determined that these devices are essentially the same. Therefore, the agency is proposing a single regulation classifying thyroid autoantibody immunological test systems into class II and is publishing the two Panel's recommendation in a proposal appearing elsewhere in this issue of the **Federal Register.**

4. The Clinical Chemistry Device Classification Panel recommended that measurement of transferrin by immunochemical methods be classified into class II. The immunology Device Classification Panel recommended that transferrin, antigen, antiserum, control; transferrin, FITC, antigen, antiserum, control; and transferrin, rhodamine, antigen, antiserum, control be classified into class II. FDA has determined that these devices are essentially the same. Therefore, the agency is proposing a single regulation classifying transferrin immunological test sytems into class II and is publishing the two Panels' recommendation in a proposal appearing elsewhere in this issue of the **Federal Register.**

5. The Clinical Chemistry Device Classification Panel recommended that measurement of ferritin by two-site solid-phase radioimmunoassay be classified into class II. The Immunology Device Classification Panel recommended that test systems for measurement of ferritin, antigen, antiserum, control be classified into class II. FDA has determined that these devices are essentially the same. Therefore, the agency is proposing a single regulation classifying ferritin

immunology test systems into class II and is publishing the two Panels' recommendation in a proposal appearing elswhere in this issue of the **Federal Register.**

6. The Clinical Chemistry Device Classification Panel recommended that measurement of immunoglobulins A, G, M, D, and E by radioimmunoassay, immunodiffusion, immunoelectrophoresis or the nephelometric method be classified into class II. The Immunology Device Classification Panel recommended that measurement of immunoglobulins A, G, M, D, and E by methods such as immunodiffusion, immunoelectrophoresis, nephelometry or radioimmunoassay be classified into class II. FDA has determined that these devices are essentially the same. Therefore, the agency is proposing a single regulation classifying immunoglobulins A, G, M, D, and E immunological test systems into class II and is publishing the two Panels' recommendation in a proposal appearing elsewhere in this issue of the **Federal Register.**

The Immunology Device Classification Panel and the Clinical Chemistry Device Classification Panel made classification recommendations concerning the following devices:

Nonradioimmunoassay systems to detect human chorionic gonadatropin.

Radioimmunoassay systems to detect human chorionic gonadotropin.

Test systems to measure human placental lactogen.

Luteinizing hormone, antigen, antiserum, control.

Lysozyme, antigen, antiserum, control.

FDA is not at this time publishing the Immunology Device Classification Panel's recommendations to classify the devices listed above. The agency will publish these recommendations, and proposed classification regulations, when it publishes the recommendations of the Clinical Chemistry Device Classification Panel.

The Microbiology Device Classification Panel and the Toxicology Device Classification Panel made classification recommendations concerning the following devices:

Chromatography for bacterial identification.

Disc agar diffusion kits to determine serum levels of antibiotics.

FDA is not at this time publishing the Microbiology Device Classification Panel's recommendations to classify the devices listed above. The agency will publish these recommendations, and proposed classification regulations, when it publishes the recommendations of the Toxicology Device Classification Panel.

Related Device Classification Regulations

The Microbiology Device Classification Panel or the Immunology Device Classification Panel made classification recommendations concerning the following devices that were published with the Hematology Device Classification Panel or the Pathology Device Classification Panel recommendations and the agency's proposed classification for these devices in the **Federal Register** of September 11, 1979 (44 FR 52950):

Device and other panel

Antithrombin III, antigen antiserum, control—Hematology.

Fibrinogen and fibrin-split products, antigen, antiserum, control—Hematology.

Stains, microbiologic, all—Pathology.

Environmental Impact

The agency has determined pursuant to 21 CFR 25.24(b)(12) (proposed December 11, 1979, 44 FR 71742) that this proposed action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513 and 701d(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)), and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposed that Chapter I of Title 21 of the Code of Federal Regulations be amended by adding new Part 866, Subpart A, to read as follows:

PART 866—MICROBIOLOGY OR IMMUNOLOGY DEVICES

Subpart A—General Provisions

Sec.

866.1 Scope.

Authority: Secs. 513 and 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c and 701(a)).

Subpart A—General Provisions

§ 866.1 Scope.

(a) This part sets forth the classification of microbiology or immunology devices intended for human use.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21 unless otherwise noted.

(c) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a premarket notification submission for a device under Part 807 cannot show merely that the device is accurately described by the section title and identification provision of a regulation in this part, but shall state why the device is substantially equivalent to other devices, as required by § 807.87.

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m., Monday through Friday.

In accordance with Executive Order 12044, the economic effects of this proposal have been carefully analyzed, and it has been determined that the proposed rulemaking does not involve major economic consequences as defined by that order. A copy of the regulatory analysis assessment supporting this determination is on file with the Hearing Clerk, Food and Drug Administration.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11737 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2124]

Medical Devices; Classification of Antimicrobial Susceptibility Test Discs

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying antimicrobial susceptibility test discs into class II (performance standards). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public

comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980 FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of antimicrobial susceptibility test discs:

1. Identification: An antimicrobial susceptibility test disc is a device that consists of antimicrobic-impregnated paper discs used to measure by a disc agar diffusion technique or a disc-broth elution technique the in vitro susceptibility of most clinically important bacterial pathogens to antimicrobial agents. In the disc-agar diffusion technique, bacterial susceptibility is ascertained by directly measuring the magnitude of a zone of bacterial inhibition around the disc on an agar surface. The disc-broth elution technique is associated with an automated rapid susceptibility test system and employs a fluid medium in which susceptibility is ascertained by photometrically measuring changes in bacterial growth resulting when antimicrobial material is eluted from the disc into the fluid medium. Test results are used in the treatment of bacterial diseases to determine the antimicrobial agent of choice. The Panel reviewed this generic type of device identified by the names "antimicrobial susceptibility test system" and "antimicrobial susceptibility test discs."

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that antimicrobial susceptibility test discs be classified into class II because there is a need for a performance standard that prescribes for these devices acceptable ranges of accuracy, precision, potency, purity, and stability and thereby minimizes the possibility that the devices may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel recognizes the importance to the clinician of antimicrobial susceptibility tests in selecting the drug of choice for patients afflicted with diseases caused by infectious microbial pathogens. The Panel also observes that results obtained with antimicrobial susceptibility test discs may be influenced by the content and pH of the culture medium, the concentration of antimicrobial agents in the test system, the concentration of the bacterial inoculum, the temperature and atmosphere of incubation, and the variation of endpoint measurements. The Panel also observes that the susceptibility test disc is an integral component of disc-agar diffusion and disc-broth elution methods and that test results are significantly influenced by the purity, stability, and content (potency) of the antimicrobial agent contained in the disc. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, purity, potency, and stability. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard (Refs. 3 and 5).

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, these devices and on the Panel's review of the literature, which disclosed variation in the manufacture of these devices regarding their identity, purity, potency, accuracy, and precision (Refs. 1, 2, and 4). Stubbs and Wicher (Ref. 1) evaluated an automated antimicrobial susceptibility test system using antimicrobial elution discs. Of 2,518 organisms examined, 651 (26 percent) showed discrepancies in response to one or more antibiotics when compared with the disc-agar diffusion method (Bauer-Kirby). Thornsberry, et al. (Ref. 2) noted that the problem of false susceptibility reports with these rapid systems usually results from the prolonged lag phase that may occur with subminimal inhibitory concentration of antimicrobial agent in certain drug/organism combinations. Rippere (Ref. 4) reported that different grades of paper used in the manufacture and assay of antibiotic diffusion discs have significant effects on the diffusion of antibiotics from the paper.

5. Risks to health: Inappropriate therapy: Failure of the device to perform satisfactorily may lead to inappropriate therapy which may place the patient at risk.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that antimicrobial susceptibility test discs be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Antimicrobial susceptibility test systems that contain antibiotics are subject to premarket approval regulations for antibiotics under section 507 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 357) (Ref. 5). Section 520(1)(4) of the act (21 U.S.C. 360j(1)(4)) provides that if a class II device was subject to the requirements of section 507 on May 28, 1976 (the enactment date of the Medical Device Amendments), these requirements shall continue to apply to the device until the effective date of a performance standard applicable to the device under section 514 of the act. Thus, antimicrobial susceptibility test systems that were then subject to the requirements of section 507 of the act continue to be subject to these requirements until the effective date of a performance standard for these devices.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons from 9 a.m. to 4 p.m., Monday through Friday.

1. Stubbs, K. G. and K. Wicher, "Laboratory Evaluation of an Automated Antimicrobial Susceptibility System," *American Journal of Clinical Pathology*, 68(6):769–777, 1977.

2. Thornsberry, C., T. L. Gavan, and E. H. Gerlach, coordinating editor J. C. Sherris, "New Developments in Antimicrobial Agent Susceptibility Testing," *Cumulative Techniques and Procedures in Clinical Microbiology (Cumitech), No. 6*, American Society for Microbiology, September 1977.

3. "Performance Standards for Antimicrobial Disc Susceptibility Tests," National Committee for Clinical Laboratory Standards, January 1976.

4. Rippere, R. A., "Effects of Paper on Performance of Antibiotic Impregnated Disks," *Journal of Pharmaceutical Sciences*, 67(3), 1978.

5. *Code of Federal Regulations*, Title 21, Part 460—Antibiotic Drugs Intended for Use in Laboratory Diagnosis of Disease, Subpart A—Susceptibility Discs, pp. 694–706, 1979.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 by adding new Subpart B including § 866.1620, to read as follows:

Subpart B—Antimicrobial Susceptibility Test Devices

§ 866.1620 Antimicrobial susceptibility test disc.

(a) *Identification.* An antimicrobial susceptibility test disc is a device that consists of antimicrobic-impregnated paper discs used to measure by a disc-agar diffusion technique or a disc-broth elution technique the in vitro susceptibility of most clinically important bacterial pathogens to antimicrobial agents. In the disc-agar diffusion technique, bacterial susceptibility is ascertained by directly measuring the magnitude of a zone of bacterial inhibition around the disc on an agar surface. The disc-broth elution technique is associated with an automated rapid susceptibility test system and employs a fluid medium in which susceptibility is ascertained by photometrically measuring changes in bacterial growth resulting when antimicrobial material is eluted from the disc into the fluid medium. Test results are used in the treatment of bacterial diseases to determine the antimicrobial agent of choice.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11738 Filed 4–21–80; 8:45 am]

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21 CFR Part 866

[Docket No. 78N–2115]

Medical Devices; Classification of Antimicrobial Susceptibility Test Powders

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying antimicrobial susceptibility test powders into class II (performance standards). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of antimicrobial susceptibility test powders:

1. Identification: An antimicrobial susceptibility test powder is a device that consists of an antimicrobial drug powder packaged in vials in specified amounts and intended for use in clinical laboratories for determining in vitro susceptibility of bacterial pathogens to these therapeutic agents. Test results are used in the treatment of bacterial diseases to determine the antimicrobial agent of choice.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that the antimicrobial susceptibility test powder be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of identity, purity, potency, and stability and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel recognizes the importance to the clinician of antimicrobial susceptibility tests in selecting the drug of choice for patients afflicted with diseases caused by infectious microbial pathogens. The Panel also observes that antimicrobial susceptibility tests are significantly influenced by the purity and strength of the antimicrobial agent. The Panel is aware of variations in the performance of these devices that may be caused by use of different manufacturing procedures and controls that affect their identity, purity, potency, and stability. The Panel believes that general controls would not provide sufficient control over the device's identity, purity, potency, and stability. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1 and 2). The Panel is aware of reference materials for the devices (Ref. 1).

5. Risks to health: Inappropriate therapy: Failure of the device to perform satisfactorily may lead to inappropriate therapy which may place the patient at risk.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that antimicrobial susceptibility test powders be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Antimicrobial susceptibility test powders that contain antibiotics are subject to premarket approval regulations for antibiotics under section 507 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 357) (Ref. 1). Section 520(1)(4) of the act (21 U.S.C. 360j(l)(4)) provides that if a class II device was subject to the requirements of section 507 on May 28, 1976 (the enactment date of the Medical Device Amendments), these requirements shall continue to apply to the device until the effective date of performance standard applicable to the device under section 514 of the act. Thus, antimicrobial susceptibility test powders that were then subject to the requirements of section 507 of the act continue to be subject to these

requirements until the effective date of a performance standard for these devices.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons from 9 a.m. to 4 p.m., Monday through Friday.

1. *Code of Federal Regulations,* Title 21, Part 460—Antibiotic Drugs Intended for Use in Laboratory Diagnosis of Disease, Subpart B–Susceptibility Powders, pp. 706–721, 1979.

2. "Biological Tests and Assays: Antibiotics—Microbial Assays," *in United States Pharmacopeia,* XIX, pp. 595–600, 1975.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart B by adding new § 866.1640, to read as follows:

§ 866.1640 Antimicrobial susceptibility test powder.

(a) *Identification.* An antimicrobial susceptibility test powder is a device that consists of an antimicrobial drug powder packaged in vials in specified amounts and intended for use in clinical laboratories for determining in vitro susceptibility of bacterial pathogens to these therapeutic agents. Test results are used in the treatment of bacterial diseases to determine the antimicrobial agent of choice.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11739 Filed 4–21–80; 8:45 am]

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21 CFR Part 866

[Docket No. 78N–2117]

Medical Devices; Classification of Culture Media for Antimicrobial Susceptibility Tests

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying culture media for antimicrobial susceptibility tests into Class II (performance standards). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATE: Comments by June 23, 1980.

FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information conerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of culture media for antimicrobial susceptibility tests:

1. Identfication: A culture medium for antimicrobial susceptibility tests is a device that consists of any medium capable of supporting the growth of the majority of bacterial pathogens that require antimicrobial susceptibility tests. The medium is free of components known to be antagonistic to the common agents for which susceptibility tests are performed in the treatment of disease.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that the culture medium for antimicrobial susceptibility tests be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, and reliability and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel notes that culture media are an integral component of antimicrobial susceptibility testing and that reproducible test results are significantly influenced by several performance properties of the medium such as pH (measure of acidity) and cation (positively charged components) content. The Panel recommends that culture media for antimicrobial susceptibility testing be classified into class II (performance standards) to assure uniformity of these properties among manufacturers. The Panel members have noted significant variation in the manufacture of these products regarding their pH and cation content. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, and reliability. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1, 2, and 3). Barry (Ref. 1) states that there is unacceptable lot-to-lot variation in the manufacture of Mueller-Hinton agar (commonly used in susceptibility tests) and that in the future this medium should be replaced with a chemically defined medium. Barry (Ref. 2) indicates that the concentration of certain cations is critically important and that most Mueller-Hinton broth commercially available needs to be supplemented to obtain correct cation concentration. Barry (Ref. 2) also suggests that each batch of Mueller-Hinton medium should be checked for proper pH before use. Studies by Sherris, et al. (Ref. 3) have also demonstrated that Mueller-Hinton agar varies from lot to lot, whether the lot comes from the same manufacturer or from different manufacturers.

5. Risks to health: Inappropriate therapy: Failure of this device to perform satisfactorily may lead to inappropriate therapy which may place the patient at risk.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that culture media for antimicrobial susceptibility tests be classified into class II (performance standards). The agency believes that a performance

standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons from 9 a.m. to 4 p.m., Monday through Friday.

1. Barry, A. L., "The Role of NCCLS in the Standardization of Antimicrobic Susceptibility Techniques," *in* "Current Techniques for Antibiotic Susceptibility Testing," Balows, A. (ed.), pp. 47–53, 1974.

2. Barry, A. L., "Dilution Tests: General Considerations," *in* "The Antimicrobic Susceptibility Test: Principles and Practices," Lea and Febiger, Publishers, Philadelphia, pp. 61–75, 1976.

3. Sherris, J. C., C. Thornsberry, C. L. Aitken, and C. N. Baker, Abstract, *International Congress of Chemotherapy*, 9th Ed., Abstract No. M523, 1975.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart B by adding new § 866.1700, to read as follows:

§ 866.1700 Culture medium for antimicrobial susceptibility tests.

(a) *Identification.* A culture medium for antimicrobial susceptibility tests is a device that consists of any medium capable of supporting the growth of the majority of bacterial pathogens that require antimicrobial susceptibility tests. The medium is free of components known to be antagonistic to the common agents for which susceptibility tests are performed in the treatment of disease.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11740 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2118]

Medical Devices; Classification of Staphylococcal Typing Bacteriophages

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying staphylococcal typing bacteriophages into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of staphylococcal typing bacteriophages:

1. Identification: A staphylococcal typing bacteriophage is a device consisting of a bacterial virus used to identify pathogenic staphylococcal bacteria through use of this bacteria's susceptibility to cell destruction by the virus. Test results are used principally for the collection of epidemiological information.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that staphylococcal typing bacteriophages be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: Epidemiological misinformation: Failure of the device to detect the presence of pathogenic staphylococcal bacteria may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that staphylococcal typing bacteriophages be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart C by adding new § 866.2050, to read as follows:

Subpart C—Microbiology Devices

§ 866.2050 Staphylococcal typing bacteriophage.

(a) *Identification.* A staphylococcal typing bacteriophage is a device consisting of a bacterial virus used to identify pathogenic staphylococcal bacteria through use of this bacteria's susceptibility to cell destruction by the virus. Test results are used principally for the collection of epidemiological information.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be

identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 5, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-11741 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 866

[Docket No. 78N-2119]

Medical Devices; Classification of Anaerobic Chambers

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying anaerobic chambers into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of anaerobic chambers:Q04

1. Identification: An anaerobic chamber is a device intended to maintain an anaerobic (oxygen free) environment that is used in the diagnosis of disease for the isolation and cultivation of anaerobic microorganisms.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from the good manufacturing practice regulation under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)) and from premarket notification under section 510(k) of the act (21 U.S.C. 360(k)).

3. Summary of reasons for recommendation: The Panel recommends that anaerobic chambers be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel recommends that the anaerobic chamber be exempt from the good manufacturing practice regulation under section 520(f) of the act because the history of user experience with the device demonstrates that application of the entire GMP would not improve the quality (i.e., safety and efficacy) of the device. The Panel also recommends that the anaerobic chamber be exempt from premarket notification procedures under section 510(k) of the act because it is a familiar device that presents no hazards to health.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that anaerobic chambers be classified into class I (general controls). The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

In response to the Panel's recommendation that manufacturers of an anaerobic chamber be exempt from section 510(k) of the act, FDA agrees with the Panel and is proposing that the manufacturer of this device be exempt from premarket notification under section 510(k) of the act and Subpart E of Part 807 of the regulations. The agency has determined that it is not necessary for the protection of the public health that FDA receive premarket notification submissions concerning an anaerobic chamber. The agency does not at this time anticipate that premarket approval will be required for this device. The agency believes that the semiannual updating of device listing under section 510(j)(2) will provide FDA with adequate notice concerning new products within this generic type of device.

In response to the Panel's recommendation that manufacturers of an anaerobic chamber be exempt from the device good manufacturing practice (GMP) regulation under section 520(f) of the act, FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files. Based on available information about current practices used in the manufacture of the device and user experience with the device, the agency has determined that application of the GMP regulation, other than §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the device. the agency believes, however, that manufacturers of an anaerobic chamber must still be required to comply with the complaint file requirements of § 820.198 to ensure that these manufacturers have adequate systems for complaint investigation and followup. The agency also believes that manufacturers of an anaerobic chamber must still be required to comply with the general requirements concerning records in § 820.180 to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart C by adding new § 866.2120, to read as follows:

§ 866.2120 Anaerobic chamber.

(a) *Identification.* An anaerobic chamber is a device intended to maintain an anaerobic (oxygen free) environment that is used in the diagnosis of disease for the isolation and cultivation of anaerobic microorganisms.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in Subpart E of Part 807. The device also is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 5, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11742 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2121]

Medical Devices; Classification of Coagulase Plasma

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying coagulase plasma into class II (performance standards). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register**.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of coagulase plasma:

1. Identification: Coagulase plasma is a device that consists of freeze-dried animal or human plasma that is used for performance of coagulase tests primarily on staphylococcal bacteria. When reconstituted, the fluid plasma is clotted by the action of the enzyme coagulase which is produced by pathogenic staphylococci. Test results are used primarily as an aid in the diagnosis of disease caused by pathogenic bacteria belonging to the genus *Staphylococcus* and provide epidemiological information on diseases caused by these microorganisms.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that coagulase plasma be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of purity and stability and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The chief sources of a staphylococcal infection are accessible human lesions, the respiratory tract, and the skin. Staphylococci can survive for a period of time outside the body in the air. The airborne infection potential is important in hospitals because a large proportion of the staff and patients carry antibiotic resistant staphylococci in the nose or throat or on the skin. Introduction of large quantities of airborne pathogenic staphylococci bacteria into newborn nurseries and surgical operating rooms may lead to serious clinical disease (e.g., abscesses in the organs). The coagulase test is a key test for differentiating the pathogenic (coagulase producing) strains of staphylococcal bacteria from the nonpathogenic strains. The Panel believes that general controls will not provide sufficient control over the device's purity and stability. The Panel believes that a performance standard will provide a reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel member's personal knowledge of, and clinical experience with, the device and upon a review of the literature (Ref. 1). The literature review disclosed appreciable lot-to-lot variations in the purity and stability of coagulase plasmas which often lead to problems of false-positive and false-negative test results. Sperber and Tatini found that the source of supply of coagulase plasma is a factor in the occurrence of a false-positive test result (Ref. 1). These investigators also noted that the coagulation in the tube test seems to involve the conversion of fibrinogen to fibrin by the coagulase enzyme complex and the coagulase-reacting factor in the plasma. They noted that if the plasma in the tube test is to be standardized, attention should be given to assuring that adequate amounts of coagulase-reacting factor (the quantity varies with the source of the plasma) and optimal amounts of fibrinogen are present, and that procedures are used to minimize the influence of any inhibitory factors present in the plasma (Ref. 1).

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of diseases caused by pathogenic staphylococci. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of pathogenic staphylococci in a patient may contribute to epidemiological misinformation. Consequently, the risk relates to the dissemination of infection to other individuals or communities.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that coagulase plasma be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls along are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seem by interested persons, from 9 a.m to 4 p.m., Monday through Friday.

1. Sperber, W. H., and S. R. Tatini, "Interpretation of the Tube Coagulases Test for Identification of Staphylococcus aureus," *Applied Microbiology*, pp. 502–505, April 1975.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart C by adding new § 866.2160, to read as follows:

§ 866.2160 Coagulase plasma.

(a) *Identification.* Coagulase plasma is a device that consists of freeze-dried

animal or human plasma that is used for performance of coagulase tests primarily on staphylococcal bacteria. When reconstituted, the fluid plasma is clotted by the action of the enzyme coagulase which is produced by pathogenic staphylococci. Test results are used primarily as an aid in the diagnosis of disease caused by pathogenic bacteria belonging to the genus *Staphylococcus* and provides epidemiological information on disease caused by these microorganisms.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written coments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m and 4 p.m. Monday through Friday.

Dated March 5, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11743 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2122]

Medical Devices; Classification of Automated Colony Counters

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying automated colony counters into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of automated colony counters:

1. Identification: An automated colony counter is a mechanical device used to determine the number of bacterial colonies present on a bacteriological culture medium contained in a petri plate. The number of colonies counted is used in the diagnosis of disease as a measure of the degree of bacterial infection.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that automated colony counters be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the measurement of the degree of bacterial infection that may cause misdiagnosis. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

Proposed Classificaton

FDA agrees with the Panel recommendation and is proposing that automated colony counters be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart C by adding new § 866.2170, to read as follows:

§ 866.2170 Automated colony counter.

(a) *Identification.* An automated colony counter is a mechanical device used to determine the number of bacterial colonies present on a bacteriological culture medium contained in a petri plate. The number of colonies counted is used in the diagnosis of disease as a measure of the degree of bacterial infection.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11744 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2123]

Medical Devices; Classification of Manual Colony Counters

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying manual colony counters into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATE: Comments by June 23, 1980. FDA proposes that the final regulation based

on this proposal become effective 30 days after the date of its publication in the **Federal Register**.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of manual colony counters:

1. Identification: A manual colony counter is a device that consists of a printed grid system superimposed on an illuminated screen. Petri plates containing bacterial colonies to be counted are placed on the screen for better viewing and ease of counting. The number of colonies counted is used in the diagnosis of disease as a measure of the degree of bacterial infection.

2. Recommended classification: Class I (general controls). The Panel recommends that manual colony counters be exempt from the good manufacturing practice regulation under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)) and from premarket notification regulations under section 510(k) of the act (21 U.S.C. 360(k)).

3. Summary of reasons for recommendation: The Panel recommends that manual colony counters be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel recommends that the manual colony counter be exempt from the good manufacturing practice regulation under section 520(f) of the act because all defects relating to the safety and effectiveness of the device are readily detectable prior to use. The Panel also recommends that the manual colony counter be exempt from premarket notification regulations under section 510(k) of the act because this is a familiar device that presents no hazards to health.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that manual colony counters be classified into class I (general controls). The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

In response to the Panel's recommendation that manufacturers of a manual colony counter be exempt from section 510(k) of the act, FDA agrees with the Panel and is proposing that the manufacturer of this device be exempt from premarket notification under section 510(k) of the act and Subpart E of Part 807 of the regulations. The agency has determined that it is not necessary for the protection of the public health that FDA receive premarket notification of submissions concerning a manual colony counter. The agency does not at this time anticipate that premarket approval will be required for this device. The agency believes that the semiannual updating of device listing under section 510(j)(2) will provide FDA with adequate notice concerning new products within this generic type of device.

In response to the Panel's recommendation that manufacturers of a manual colony counter be exempt from the device good manufacturing practice (GMP) regulation under section 520(f) of the act, FDA is proposing that a manufacturer of this device be exempt, in the manufacture of a device, from all requirements in the GMP regulation except § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files. Based on available information about current practices used in the manufacture of the device and user experience with the device, the agency has determined that application of the GMP regulation, other than §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the device. The agency believes, however, that manufacturers of a manual colony counter must still be required to comply with the complaint file requirements of § 820.198 to ensure that these manufacturers have adequate systems for complaint investigation and followup. The agency also believes that manufacturers of a manual colony counter must still be required to comply with the general requirements concerning records in § 820.180 to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart C by adding new § 866.2180, to read as follows:

§ 866.2180 Manual colony counter.

(a) *Identification:* A manual colony counter is a device that consists of a printed grid system superimposed on an illuminated screen. Petri plates containing bacterial colonies to be counted are placed on the screen for better viewing and ease of counting. The number of colonies counted is used in the diagnosis of disease as a measure of the degree of bacterial infection.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in Subpart E of Part 807. The device also is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 5, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11745 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2124]

Medical Devices; Classification of Multipurpose Culture Media

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying multipurpose culture media into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of the publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of multipurpose culture media:

1. Identification: A multipurpose culture medium is a device that consists primarily of liquid and/or solid biological materials used for the cultivation and identification of several types of microorganisms without the need of additional nutritional supplements. Test results aid in the diagnosis of disease and also provide epidemiological information on diseases caused by these microorganisms.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that multipurpose culture media be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel members have observed lot-to-lot variation in the performance of these media. The Panel believes, however, that lot-to-lot variations in product performance resulting from manufacturing procedures can be adequately controlled by manufacturer compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of diseases caused by human pathogen(s). Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of a suspected pathogen(s) may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that multipurpose culture media be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart C by adding new § 866.2300, to read as follows:

§ 866.2300 Multipurpose culture medium.

(a) *Identification.* A multipurpose culture medium is a device that consists primarily of liquid and/or solid biological materials used for the cultivation and identification of several types of microorganisms without the need of additional nutritional supplements. Test results aid in the diagnosis of disease and also provide epidemiological information on diseases caused by these microorganisms.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 5, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11746 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2125]

Medical Devices; Classification of Differential Culture Media

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying differential culture media into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of differential culture media:

1. Identification: A differential culture medium is a device that consists primarily of liquid and/or solid biological materials used

to cultivate and identify different types of microorganisms. The identification of these microorganisms is accomplished by the addition of a specific biochemical component(s) to the medium. Microorganisms are identified by a visible change (e.g., a color change) in a specific biochemical component(s) which indicates that specific metabolic reactions have occurred. Test results aid in the diagnosis of disease and also provide epidemiological information on diseases caused by these microorganisms.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that differential culture media be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel members have observed lot-to-lot variation in the performance of these media.

The Panel believes, however, that lot-to-lot variation in product performance resulting from manufacturing procedures can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of diseases caused by a human pathogen(s). Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of a suspected pathogen(s) may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that differential culture media be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart C by adding new § 866.2320, to read as follows:

§ 866.2320 Differential culture medium.

(a) *Identification.* A differential culture medium is a device that consists primarily of liquid and/or solid biological materials used to cultivate and identify different types of microorganisms. The identification of these microorganisms is accomplished by the addition of a specific biochemical component(s) to the medium. Microorganisms are identified by a visible change (e.g., a color change) in a specific biochemical component(s) which indicates that specific metabolic reactions have occurred. Test results aid in the diagnosis of disease and also provide epidemiological information on diseases caused by these microorganisms.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 5, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11747 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2126]

Medical Devices; Classification of Enriched Culture Media

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying enriched culture media into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of enriched culture media:

1. Identification: An enriched culture medium is a device that consists primarily of liquid and/or solid biological materials used to cultivate and identify fastidious microorganisms (having complex nutritional requirements). The device consists of a relatively simple basal medium enriched by the addition of such nutritional components as blood, blood serum, vitamins, and extracts of plant or animal tissues. The device is used in the diagnosis of disease caused by pathogenic microorganisms and also provides epidemiological information on these diseases.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that enriched culture media be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel members have observed lot-to-lot variation in the performance of these media. The Panel believes, however, that lot-to-lot variation in product performance resulting from manufacturing procedure can be adequately controlled by manufacturer compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowlege of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of diseases caused by a human pathogen(s). In appropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological

misinformation: Failure of the device to detect the presence of a suspected pathogen(s) may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that enriched culture media be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart C by adding new § 866.2330, to read as follows:

§ 866.2330 Enriched culture medium.

(a) *Identification.* An enriched culture medium is a device that consists primarily of liquid and/or solid biological materials used to cultivate and identify fastidious microorganisms (having complex nutritional requirements). The device consists of a relatively simple basal medium enriched by the addition of such nutritional components as blood, blood serum, vitamins, and extracts of plant or animal tissues. The device is used in the diagnosis of disease caused by pathogenic microoganisms and also provides epidemiological information on these diseases.

(b) *Classification.* Class I (general controls)

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 5, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 11748 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

21 CFR Part 866

[Docket No. 78N–2127]

Medical Devices; Classification of Microbiological Assay Culture Media

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying microbiological assay culture media into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of microbiological assay culture media:

1. Identification: A microbiological assay culture medium is a device that consists primarily of liquid and/or solid biological materials used to cultivate selected test microorganisms in order to identify and measure by microbiological procedures the presence and concentration of certain substances (e.g., amino acids, antimicrobial agents, vitamins) in a patient's serum. The presence and/or concentration of these substances is measured by their ability to promote or inhibit the growth of the test organism in the inoculated medium. Test results aid in the diagnosis of disease resulting from either deficient or excessive amounts of these substances in a patient's serum. Test results may also be used to monitor therapy, e.g., in the administration of certain antimicrobial drugs.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that microbiological assay culture media be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of a disease state. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that microbiological assay culture media be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart C by adding new § 866.2350, to read as follows:

§ 866.2350 Microbiological assay culture medium.

(a) *Identification.* A microbiological assay culture medium is a device that consists primarily of liquid and/or solid biological materials used to cultivate selected test microorganisms in order to identify and measure by microbiological procedures the presence and concentration of certain substances (e.g., amino acids, antimicrobial agents, vitamins) in a patient's serum. The presence and/or concentration of these substances is measured by their ability to promote or inhibit the growth of the test organism in the inoculated medium. Test results aid in the diagnosis of disease resulting from either deficient or excessive amounts of these substances in a patient's serum. Tests results may also be used to monitor therapy, e.g., in the administration of certain antimicrobial drugs.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 5, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11749 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2128]

Medical Devices; Classification of Selective Culture Media

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying selective culture media into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of selective culture media:

1. Identification: A selective culture medium is a device that consists primarily of liquid and/or solid biological materials used to cultivate and identify certain microorganisms. The device contains one or more components that suppress the growth of certain microorganisms while either promoting or not affecting the growth of other microorganisms. The device aids in the diagnosis of disease caused by pathogenic microorganisms and also provides epidemiological information on these diseases.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reason for recommendation: The Panel recommends that selective culture media be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel members have observed lot-to-lot variation in the performance of these media. The Panel believes, however, that lot-to-lot variation in product performance resulting from manufacturing procedures can be adequately controlled by manufacturer compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of diseases caused by a human pathogen(s). Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of a suspected pathogen(s) may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that selective culture media be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart C by adding new § 866.2360, to read as follows:

§ 866.2360 Selective culture medium.

(a) *Identification.* A selective culture medium is a device that consists primarily of liquid and/or solid biological materials used to cultivate and identify certain microorganisms. The device contains one or more components that suppress the growth of certain microorganisms while either promoting or not affecting the growth of other microorganisms. The device aids in the diagnosis of disease caused by pathogenic microorganisms and also provides epidemiological information on these diseases.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments, are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 5, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11750 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2129]

Medical Devices; Classification of Transport Culture Media

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying transport culture media into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After

considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of transport culture media:

1. Identification: A transport culture medium is a device that consists of a semi-solid, usually non-nutrient, medium that maintains the viability of suspected pathogens contained in patient specimens while in transit from the specimen collection area to the laboratory. The device aids in the diagnosis of disease caused by pathogenic microorganisms and also provides epidemiological information on these diseases.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that transport culture media be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel members have observed lot-to-lot variation in these products regarding their ability to maintain the viability of microorganisms. The Panel believes, however, that any variation in product performance resulting from manufacturing procedures can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of disease caused by a human pathogen(s). Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of a suspected pathogen(s) may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that transport culture media be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart C by adding new § 866.2390, to read as follows:

§ 866.2390. Transport culture medium.

(a) *Identification.* A transport culture medium is a device that consists of a semisolid, usually non-nutrient, medium that maintains the viability of suspected pathogens contained in patient specimens while in transit from the specimen collection area to the laboratory. The device aids in the diagnosis of disease caused by pathogenic microorganisms and also provides epidemiological information on these diseases.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 5, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11751 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

21 CFR Part 866

[Docket No. 78N–2130]

Medical Devices; Classification of Culture Media for Pathogenic Neisseria Spp.

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying culture media for pathogenic *Neisseria* spp. into class II (performance standards). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of culture media for pathogenic *Neisseria* spp.:

1. Identification: A culture medium for pathogenic *Neisseria* spp. is a device that consists primarily of liquid and/or solid biological materials used to cultivate and identify pathogenic *Neisseria* spp. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus *Neisseria,* such as epidemic cerebrospinal meningitis, other meningoccoccal disease, and gonorrhea, and also provides epidemiological information on these diseases.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for the recommendation: The Panel recommends that culture media for pathogenic *Neisseria* spp. be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of sensitivity, specificity and nutritional properties, and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily.

Neisseria meningitidis is the prominent cause of epidemic cerebrospinal meningitis, an inflammation of brain and spinal cord membranes. Meningococcemia is a form of neural membrane disease involving the membranes which envelop the brain and spinal cord that may result from invasion of the bloodstream by *Neisseria meningitidis.* The resulting blood infection may cause massive hemorrhage near the kidneys accompanied by widespread blood coagulation within the blood vessels. If the above-described conditions are undetected and untreated, the outcome is usually fatal. Gonorrhea is a highly infectious veneral disease usually transmitted by sexual intercourse, but which also may be transmitted to a newborn by an infected mother. Gonorrhea caused by *Neisseria gonorrhoeae* is characterized by acute pus-producing inflammation of the urethra in men and inflammation of the cervix in women. Infection may also spread to the joints, resulting in a condition called gonococcal arthritis. The Panel observes that gonorrhea is epidemic in certain areas of the United States. Erradication of the disease is complicated by asymptomatic carriers who can be identified by use of diagnostic procedures that include an effective culture medium to identify *Neisseria gonorrhoeae* in patient specimens.

The Panel believes that general controls would not provide sufficient control over the device's sensitivity, specificity, and nutritional properties. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation of the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1 through 6). The Panel's literature review disclosed appreciable variation in the manufacture of this device regarding its sensitivity, specificity, and nutritional properties for *Neisseria* spp. cultivation and identification (Refs. 1 through 6). Isolation rates for Thayer-Martin medium, the most widely used medium, have been reported to range from 40 percent (Ref. 1) to 90 percent (Ref. 2). Brorson, et al. (Ref. 3) reported a proportion of gonococci which are inhibited by the effects of vancomycin, an antibiotic contained in Thayer-Martin media, thereby decreasing the sensitivity of the media. Jones and Talley (Ref. 4) observed that different commercial agars varied widely in their toxicity for *Neisseria gonorrhoeae.* Kousa, et al. (Ref. 5) observed differences in sensitivities between a gonococcal transport medium and Thayer-Martin medium. Knapp and Holmes (Ref. 6) reported that 39 percent of the isolates from nondisseminated gonococcal infections in Seattle, Washington, had nutritional requirements not provided for in cystine-trypticase agar media, thus pointing out the need for performance standards which would address the nutritional requirements of gonococci.

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of diseases caused by *Neisseria* spp. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of pathogenic *Neisseria* spp. may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that culture media for pathogenic *Neisseria* spp. be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Johnson, D. W., K. K. Holmes, P. A. Kvale, C. W. Halverson, and W. P. Hirsch, "An Evaluation of Gonorrhea Case Finding in the Chronically Infected Female," *American Journal of Epidemiology,* 90:438–448, 1969.

2. Caldwell, J. G., E. V. Price, G. J. Pazin, and C. E. Cornelius, III, "Sensitivity and Reproducibility of Thayer-Martin Culture Medium in Diagnosing Gonorrhea in Women," *American Journal of Obstetrics and Gynecology,* 109:463–468, 1971.

3. Brorson, J. E., I. Holmberg, B. Nygren, and S. Seeberg, "Vancomycin-Sensitive Strains of *Neisseria gonorrhoeae:* A Problem for the Diagnostic Laboratory," *British Journal of Venereal Disease,* 49:452–453, 1973.

4. Jones, R. T. and R. S. Talley, "Simplified Complete Medium for the Growth of *Neisseria gonorrhoeae," Journal of Clinical Microbiology,* 5(1):9–14, 1977.

5. Kousa, M., O. V. Renkonen, U. Kiistala, and A. Lassus, "Transgrow (Clinicult) in the Laboratory Diagnosis of gonorrhea," *British Journal of Venereal Disease,* 49:450–451, 1973.

6. Knapp, J. S. and K. K. Holmes, "Disseminated Gonococcal Infections Caused by *Neisseria gonorrhoeae* with Unique Nutritional Requirements," *Journal of Infectious Diseases,* 132:204–208, 1975.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart C by adding new § 866.2410 to read as follows:

§ 866.2410 Culture medium for pathogenic Neisseria spp.

(a) *Identification.* A culture medium for pathogenic *Neisseria* spp. is a device that consists primarily of liquid and/or solid biological materials used to cultivate and identify, pathogenic *Neisseria* spp. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus *Neisseria,* such as epidemic cerebrospinal meningitis, other meningoccoccal disease, and gonorrhea, and also provides epidemiological information on this microorganism.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 5, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11752 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2131]

Medical Devices; Classification of Automated Medium Dispensing and Stacking Devices

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying automated medium dispensing and stacking devices into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of automated medium dispensing and stacking devices:

1. Identification: An automated medium dispensing and stacking device is a mechanical device used to dispense a microbiological culture medium into petri dishes followed by the mechanical stacking of the petri dishes. This device aids in the diagnosis of diesease.

2. Recommended classification: Class I (general controls). The Panel recommends that automated medium dispensing and stacking devices be exempt from the good manufacturing practice regulation under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)) and from the premarket notification regulations under section 510(k) of the act.

3. Summary of reasons for recommendation: The Panel recommends that automated medium dispensing and stacking devices be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel recommends that automated medium dispensing and stacking devices be exempt from the good manufacturing practice regulation under section 520(f) of the act because all defects relating to the safety and effectiveness of the device would be readily detectable before use. The Panel also recommends that automated medium dispensing and stacking devices be exempt from premarket notification regulations under section 510(k) of the act because this is a familiar device that presents no hazards to health.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that automated medium dispensing and stacking devices be classified into class I (general controls). The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

In response to the Panel's recommendation that manufacturers of an automated medium dispensing and stacking device be exempt from section 510(k) of the act, FDA agrees with the Panel and is proposing that the manufacturer of this device be exempt from premarket notification under section 510(k) of the act and Subpart E of Part 807 of the regulations. The agency has determined that it is not necessary for the protection of the public health that FDA receive premarket notification of submissions concerning an automated medium dispensing and stacking device. The agency does not at this time anticipate that premarket approval will be required for this device. The agency believes that the semiannual updating of device listing under section 510(j)(2) will provide FDA with adequate notice concerning new products within this generic type of device.

In response to the Panel's recommendation that manufacturers of an automated medium dispensing and stacking device be exempt from the device good manufacturing practice (GMP) regulation under section 520(f) of the act, FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files. Based on available information about current practices used in the manufacture of the device and user experience with the device, the agency has determined that application of the GMP regulation, other than §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the device. The agency believes, however, that manufacturers of an automated medium dispensing and stacking device must still be required to comply with the complaint file requirements of § 820.198 to ensure that these manufacturers have adequate systems for complaint investigation and followup. The agency also believes that manufacturers of an automated medium dispensing and stacking device must still be required to comply with the general requirements concerning records in § 820.180 to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart C by adding new § 866.2440 as follows:

§ 866.2440 Automated medium dispensing and stacking device.

(a) *Identification.*—An automated medium dispensing and stacking device is a mechanical device used to dispense a microbiological culture medium into petri dishes followed by the mechanical stacking of the petri dishes. This device aids in the diagnosis of disease.

(b) *Classification.*—Class I (general controls). This device is exempt from the premarket notification procedures in Subpart E of Part 807. The device also is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments

may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 5, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-11753 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 866

[Docket No. 78N-2132]

Medical Devices; Classification of Supplements for Culture Media

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying supplements for culture media into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of supplements for culture media:

1. Identification: A supplement for culture media is a device, such as a vitamin or sugar mixture, that is added to a solid or liquid basal culture medium to produce a desired formulation and that is used to enhance the growth of fastidious microorganisms (having complex nutritional requirements). This device aids in the diagnosis of diseases caused by pathogenic microorganisms.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that supplements for culture media be classified into class I because the Panel believes general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel members have observed lot-to-lot variation in the performance of these supplements. The Panel believes, however, that lot-to-lot variation in product performance resulting from manufacturing procedures can be adequately controlled by manufacturer compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of diseases caused by human pathogens. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that supplements for culture media be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(1))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart C by adding new § 866.2450, to read as follows:

§ 866.2450 Supplement of culture media.

(a) *Identification.* A supplement for culture media is a device, such as a vitamin or sugar mixture, that is added to a solid or liquid basal culture medium to produce a desired formulation and that is used to enhance the growth of fastidious microorganisms (having complex nutritional requirements). This device aids in the diagnosis of diseases caused by pathogenic microorganisms.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 5, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-11754 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 866

[Docket No. 78N-2133]

Medical Devices; Classification of Quality Control Kits for Culture Media

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying quality control kits for culture media into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of quality control kits for culture media:

1. Identification: A quality control kit for culture medium is a device that consists of paper discs, each impregnated with a specified, freeze-dried viable microorganism, used to determine if a given culture medium is able to support the growth of that microorganism(s). The device aids in the diagnosis of disease caused by pathogenic microorganisms and also provides epidemiological information on these diseases.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that quality control kits for culture media be classified into class I because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of this device to perform satisfactorily may lead to the use of faulty culture media for diagnostic purposes. Use of faulty culture media may result in failure to detect a suspected pathogen(s), thereby contributing to a misdiagnosis and inappropriate therapy. (b) Epidemiological misinformation: Failure of the device to detect the presence of a suspected pathogen(s) may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that quality control kits for culture media be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1). The Commissioner of Food and Drugs proposes to amend Part 866 in Subpart C by adding new § 866.2480, to read as follows:

§ 866.2480 Quality control kit for culture media.

(a) *Identification.* A quality control kit for culture media is a device that consists of paper discs, each impregnated with a specified, freeze-dried viable microorganism, used to determine if a given culture medium is able to suport the growth of that microorganism(s). The device aids in the diagnosis of disease caused by pathogenic microorganisms and also provides epidemiological information on these diseases.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 5, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11755 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2134]

Medical Devices; Classification of Microtiter Diluting and Dispensing Devices

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying microtiter diluting and dispensing devices into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of microtiter diluting and dispensing devices:

1. Identification: A microtiter diluting and dispensing device is a mechanical device used to dispense and/or serially dilute biological or chemical reagents in very small quantities for use in a variety of diagnostic procedures.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that microtiter diluting and dispensing devices be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of disease caused by human pathogen(s). Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that microtiter diluting and dispensing devices be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority

delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart C by adding new § 866.2500, to read as follows:

§ 866.2500 Microtiter diluting and dispensing device.

(a) *Identification.* A microtiter diluting and dispensing device is a mechanical device used to dispense and/or serially dilute biological or chemical reagents in very small quantities for use in a variety of diagnostic procedures.

(b) *Classification.,* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 6, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11756 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2135]

Medical Devices; Classification of Microbiological Incubators

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying microbiological incubators into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of microbiological incubators:

1. Identification: A microbiological incubator is a device with various chambers and/or water-filled compartments in which controlled environmental conditions, particularly temperature, are maintained for the cultivation of microorganisms. The device aids in the diagnosis of disease.

2. Recommended classification: Class I (general controls). The Panel recommends that microbiological incubators be exempt from the good manufacturing practice regulation under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)) and from premarket notification under section 510(k) of the act (21 U.S.C. 360(k)).

3. Summary of reasons for recommendation: The Panel recommends that microbiological incubators be classified into class I because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel recommends that the microbiological incubators be exempt from good manufacturing practice regulations under section 520(f) of the act because all defects relating to the safety and effectiveness of the device would be readily detectable prior to use. The Panel also recommends that microbiological incubators be exempt from premarket notification regulations under section 510(k) of the act because this is a familiar device that presents no hazards to health.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that microbiological incubators be classified into class I (general controls). The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

In response to the Panel's recommendation that manufacturers of microbiological incubators be exempt from section 510(k) of the act, FDA agrees with the Panel and is proposing that the manufacturer of this device be exempt from premarket notification under section 510(k) of the act and Subpart E of Part 807 of the regulations. The agency has determined that it is not necessary for the protection of the public health that FDA receive premarket notification submissions concerning microbiological incubators. The agency does not at this time anticipate that premarket approval will be required for this device. The agency believes that the semiannual updating of device listing under section 510(j)(2) will provide FDA with adequate notice concerning new products within this generic type of device.

In response to the Panel's recommendation that manufacturers of a microbiological incubator be exempt from the device good manufacturing practice (GMP) regulation under section 510(f) of the act, FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files. Based on available information about current practices used in the manufacture of the device and user experience with the device, the agency has determined that application of the GMP regulation, other than §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the device. The agency believes, however, that manufacturers of a microbiological incubator must still be required to comply with the complaint file requirements of § 820.198 to ensure that these manufacturers have adequate systems for complaint investigation and follow-up. The agency also believes that manufacturers of a microbiological incubator must still be required to comply with the general requirements concerning records in § 820.180 to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart C by adding new § 866.2540 as follows:

§ 866.2540 Microbiological incubator.

(a) *Identification.* A microbiological incubator is a device with various chambers and/or water-filled compartments in which controlled environmental conditions, particularly temperature, are maintained for the cultivation of microorganisms. The device aids in the diagnosis of disease.

(b) *Classification.* Class I (general controls). This device is exempt from premarket notification regulations in Subpart E of Part 807. The device also is exempt from the good manufacturing practice regulation in Part 820 with the exceptions of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 6, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11757 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2136]

Medical Devices; Classification of Microbial Growth Monitors

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Asministration (FDA) is issuing for public comment a proposed regulation classifying microbial growth monitors into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal eslewhere is this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of microbial growth monitors:

1. Identification: A microbial growth monitor is a device that measures the concentration of bacteria suspended in a liquid medium by measuring changes in light scattering properties, optical density, electrical impedance, or by making direct bacterial counts. The device aids in the diagnosis of disease.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that microbial growth monitors be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices.

4. Summary of data on which the recommendation is based: The Panel based its recommendation of the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of disease caused by a human pathogen(s). Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that microbial growth monitors be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart C by adding new § 866.2560, to read as follows:

§ 866.2560 Microbial growth monitor.

(a) *Identification.* A microbial growth monitor is a device that measures the concentration of bacteria suspended in a liquid medium by measuring changes in light scattering properties, optical density, electrical impedance, or by making direct bacterial counts. The device aids in the diagnosis of disease.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 6, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 11758 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2137]

Medical Devices; Classification of Gas-Generating Devices

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying gas-generating devices into class I (general controls). FDA is also publishing the recommendation of the

Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of gas-generating devices:

1. Identification: A gas-generating device is a device that produces predetermined amounts of selected gases to be used in a closed chamber in order to establish suitable atmospheric conditions for cultivation of microorganisms with special atmospheric requirements. The device aids in the diagnosis of disease.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that gas-generating devices be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of diseases caused by a human pathogen(s). Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that gas-generating devices be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart C by adding new § 866.2580 as follows:

§ 866.2580 Gas-generating device.

(a) *Identification.* A gas-generating device is a device that produces predetermined amounts of selected gases to be used in a closed chamber in order to establish suitable atmospheric conditions for cultivation of microorganisms with special atmospheric requirements. The device aids in the diagnosis of disease.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 6, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11759 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2138]

Medical Devices; Classification of Wood's Fluorescent Lamps

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying Wood's fluorescent lamps into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of Wood's fluorescent lamps:

1. Identification: A Wood's fluorescent lamp is a device used to detect fluorescent materials (e.g., fluorescein pigment produced by certain microorganisms) as an aid in the identification of these microorganisms. The device aids in the diagnosis of disease.

2. Recommended classification: Class I (general controls). The Panel recommends that Wood's fluorescent lamps be exempt from the good manufacturing practice regulation under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)) and from premarket notification under section 510(k) of the act (21 U.S.C. 360(k)).

3. Summary of reasons for recommendation: The Panel recommends that Wood's fluorescent lamps be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel recommends that Wood's fluorescent lamps be exempt from the good manufacturing practice regulation under section 520(f) of the act because all defects relating to the safety and effectiveness of the device would be readily detectable prior to use. The Panel also recommends that this device be exempt from premarket notification regulations under section 510(k) of the act because it is a

familiar device that presents no hazards to health.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that Wood's fluorescent lamps be classified into class I (general controls). The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

In response to the Panel's recommendation that manufacturers of a Wood's fluorescent lamp be exempt from section 510(k) of the act, FDA agrees with the Panel and is proposing that the manufacturer of this device be exempt from premarket notification under section 510(k) of the act and Subpart E of Part 807 of the regulations. The agency has determined that it is not necessary for the protection of the public health that FDA receive premarket notification submissions concerning a Wood's fluorescent lamp. The agency does not at this time anticipate that premarket approval will be required for this device. The agency believes that the semiannual updating of device listing under section 510(j)(2) will provide FDA with adequate notice concerning new products within this generic type of device.

In response to the Panel's recommendation that manufacturers of a Wood's fluorescent lamp be exempt from the device good manufacturing practice (GMP) regulation under section 520(f) of the act, FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files. Based on available information about current practices used in the manufacture of the device and user experience with the device, the agency has determined that application of the GMP regulation, other than §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the device. The agency believes, however, that manufacturers of a Wood's fluorescent lamp must still be required to comply with the complaint file requirements of § 820.198 to ensure that these manufacturers have adequate systems for complaint investigation and followup. The agency also believes that manufacturers of a Wood's fluorescent lamp must still be required to comply with the general requirements concerning records in § 820.180 to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart C by adding new § 866.2600, to read as follows:

§ 866.2600 Wood's fluorescent lamp.

(a) *Identification.* A Wood's fluorescent lamp is a device used to detect fluorescent materials (e.g., fluorescein pigment produced by certain microorganisms) as an aid in the identification of these microorganisms. The device aids in the diagnosis of disease.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in Subpart E of Part 807. The device also is exempt from the good manufacturing practice regulation in Part 820 with the exceptions of § 820.180, with respect to general requirements concerning records, and § 820.198 with respect to complaint files.

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 6, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11760 Filed 4–21–80; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 866

[Docket No. 78N–2139]

Medical Devices; Classification of Microorganism Differentiation and Identification Devices

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying microorganism differentiation and identification devices into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of microorganism differentiation and identification devices:

1. Identification: A microorganism differentiation and identification device is a device that consists of one or more components (e.g., differential culture media, biochemical reagents, and/or paper discs or paper strips impregnated with test reagents) that are usually contained in individual compartments and that are used to differentiate and identify selected microorganisms or groups or microorganisms. The device aids in the diagnosis of disease.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that microorganism differentiation and identification devices be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of diseases caused by a human pathogen(s). Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that microorganism differentiation and identification devices be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart C by adding new § 866.2660 to read as follows:

§ 866.2660 Microorganism differentiation and identification device.

(a) *Identification.* A microorganism differentiation and identification device is a device that consists of one or more components (e.g., differential culture media, biochemical reagents, and/or paper discs or paper strips impregnated with test reagents) that are usually contained in individual compartments and that are used to differentiate and identify selected micro-organisms. The device aids in the diagnosis of disease.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11761 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78–N–2140]

Medical Devices; Classification of Automated Zone Readers

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying automated zone readers into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of automated zone readers:

1. Identification: An automated zone reader is a mechanical device used to measure zone diameters of microbial growth inhibition (or exhibition), such as those observed on the surface of certain culture media used in disc-agar diffusion antimicrobial susceptibility tests. The device aids in the diagnosis of disease.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that automated zone readers be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panal members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of diseases caused by a human pathogen(s). Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that automated zone readers be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart C by adding new § 866.2850, to read as follows:

§ 866.2850 Automated zone reader.

(a) *Identification.* An automated zone reader is a mechanical device used to measure zone diameters of microbial growth inhibition (or exhibition), such as those observed on the surface of certain culture media used in disc-agar diffusion antimicrobial susceptibility tests. The device aids in the diagnosis of disease.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket

number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 6, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-11762 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 866

[Docket No. 78N-2141]

Medical Devices; Classification of Specimen Collection and Transport Devices

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying specimen collection and transport devices into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of specimen collection and transport devices:

1. Identification: A specimen collection and transport device is a sterile specimen collecting chamber that preserves the viability of microorganisms during storage following collection and transport from the specimen collecting area to the laboratory. The device aids in the diagnosis of disease caused by pathogenic microorganisms and also provides epidemiological information on these diseases.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that specimen collection and transport devices be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of diseases caused by a human pathogen(s). Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to preserve the viability of a suspected pathogen may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that specimen collection and transport devices be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart C by adding new § 866.2900, to read as follows:

§ 866.2900 Specimen collection and transport device.

(a) *Identification.* A specimen collection and transport device is a sterile specimen collecting chamber that preserves the viability of microorganisms during storage following collection and transport from the specimen collecting area to the laboratory. The device aids in the diagnosis of disease caused by pathogenic microorganisms and also provides epidemiological information on these diseases.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 6, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-11763 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 866

[Docket No. 78N-2282]

Medical Devices; Classification of "Acinetobacter Calcoaceticus" Serological Reagents

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Acinetobacter calcoaceticus* serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of *Acinetobacter calcoaceticus* serological reagents:

1. Identification: *Acinetobacter calcoaceticus* serological reagents are devices that consist of *Acinretobacter calcoaceticus* antigens and antisera used to identify this bacterium from cultured isolates dervied from clinical specimens. The identification aids in the diagnosis of disease caused by the bacterium *Acinetobacter calcoaceticus* and provides epidemiological information on disease caused by this microorganism. This organism becomes pathogenic in patients with burns or with immunologic deficiency, and infection can result in sepsis (blood poisoning).

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that *Acinetobacter calcoaceticus* serological reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel noted variation in the manufacture of these reagents with respect to their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedure can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and on a history of satisfactory performance of the devices.

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of disease cause by *Acinetobacter calcoaceticus*. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

(b) Epidemiological misinformation: Failure of the device to detect the presence of *Acinetobacter calcoaceticus* may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that *Acinetobacter calcoaceticus* serological reagents be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 by adding new Subpart D consisting of § 866.3010, to read as follows:

Subpart D—Serological Reagents

§ 866.3010 Acinetobacter calcoaceticus serological reagents.

(a) *Identification. Acinetobacter calcoaceticus* serological reagents are devices that consist of *Acinetobacter calcoaceticus* antigens and antisera used to identify this bacterium from cultured isolates derived from clincial specimens. The identification aids in the diagnosis of disease caused by the bacterium *Acinetobacter calcoaceticus* and provides epidemiological information on disease caused by this microorganism. This organism becomes pathogenic in patients with burns or with immunologic deficiency, and infection can result in sepsis (blood poisoning).

(b) *Classification.* Class I (general controls.)

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockvill, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 6, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 11764 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

21 CFR Part 866

[Docket No. 78N–2142]

Medical Devices; Classification of Adenovirus Serological Reagents

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying adenovirus serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of adenovirus serological reagents:

1. Identification: Adenovirus serological reagents are devices that consist of antigens and antisera that are used in serological tests to identify adenovirus antibodies in a patient's serum. Additionally, some of these reagents consist of adenovirus antisera conjugated with a fluorescent dye and are used to identify adenoviruses directly from clinical specimens. The identification aids in the diagnosis of diseases caused by adenovirus infections and provides epidemiological information on these diseases. Adenovirus infections may cause pharyngitis (inflammation of the throat),

acute respiratory diseases, and certain external diseases of the eye (e.g., conjunctivitis).

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that adenovirus serological reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The panel recognizes that a definitive diagnosis of adenovirus infection by serological methods is often retrospective since the patient generally recovers (or succumbs) from the illness before the serodiagnosis can be made. The Panel also notes that there is no specific treatment at this time for these diseases because there is a lack of available antiviral drug therapy. Consequently, the risk of an incorrect diagnosis relates primarily to the dissemination of infection to other individuals or communities. The Panel has noted variation in the manufacture of these reagents regarding their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedure can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and on a history of satisfactory performance of the devices.

5. Risks to health: Epidemiological misinformation: Failure of the devices to detect the presence of adenoviruses may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates primarily to the dissemination of infection to other individuals or communities.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that adenovirus serological reagents be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3020, to read as follows:

§ 866.3020 Adenovirus serological reagents.

(a) *Identification.* Adenovirus serological reagents are devices that consist of antigens and antisera that are used in serological tests to identify adenovirus antibodies in a patient's serum. Additionally, some of these reagents consist of adenovirus antisera conjugated with a fluorescent dye and are used to identify adenoviruses directly from clinical specimens. The identification aids in the diagnosis of diseases caused by adenoviruses and provides epidemiological information on these diseases. Adenovirus infections may cause pharyngitis (inflamation of the throat), acute respiratory diseases, and certain external diseases of the eye (e.g., conjunctivitis).

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identifed with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 6, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11765 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2143]

Medical Devices; Classification of "Arizona" spp., Serological Reagents

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Arizona* spp. serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comment, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of *Arizona* spp. serological reagents:

1. Identification: *Arizona* spp. serological reagents are devices that consist of antisera and antigens used to identify *Arizona* spp. in cultured isolates derived from clinical specimens. The identification aids in the diagnosis of desease caused by bacteria belonging to the genus *Arizona* and provides epidemiological information on diseases caused by these microorganisms. *Arizona* spp. can cause gastroenteritis (food poisoning) and sepsis (blood poisoning).

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that *Arizona* spp. serological reagents be classified into class I because the Panel believes that general controls are sufficent to provide reasonable assurance of the safety and effectiveness of these devices. The panel has noted variation in the manufacture of these reagents regarding their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedure can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulations.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the panel members' personal knowledge of, and clinical experience with, the devices and on a history of satisfactory performance of the device.

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the devices to perform satisfactorily may lead to an error in the diagnosis of disease caused by *Arizona* spp., including gastroenteritis and blood poisoning. Inappropriate therapy based on

inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of *Arizona* spp. may contribute to epidemiological misinformation. Consequently the risk of incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs Proposes to amend Part 866 in Subpart D by adding new § 866.3935, to read as follows:

§ 866.3935 Arizona spp. serological reagents.

(a) *Identification. Arizona* spp. serological reagents are devices that consist of antisera and antigens used to identify *Arizona* spp. in cultured isolates derived from clinical specimens. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus *Arizona* and provides epidemiological information on diseases caused by these microorganisms. *Arizona* spp. can cause gastroenteritis (food poisoning) and sepsis (blood poisoning).

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 6, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11786 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

21 CFR Part 866

[Docket No. 78N–2144]

Medical Devices; Classification of Aspergillus spp. Serological Reagents

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Aspergillus* spp. serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of *Aspergillus* spp. serological reagents:

1. Identification: *Aspergillus* spp. serological reagents are devices that consist of antigens and antisera used in various serological tests to identify *Aspergillus* spp. antibodies in a patient's serum. The identification aids in the diagnosis of aspergillosis caused by fungi belonging to the genus *Aspergillus.* Aspergillosis is a disease marked by inflammatory granulomatous (tumor-like) lesions in the skin, ear, eyeball cavity, nasal sinuses, lungs, and occasionally the bones.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that *Aspergillus* spp. serological reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel has noted variation in the manufacture of these reagents regarding their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedure can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the devices to perform satisfactorily may lead to an error in the diagnosis of aspergillosis. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that *Aspergillus* spp. serological reagents be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3040, to read as follows:

866.3040 Aspergillus spp. serological reagents.

(a) *Identification. Aspergillus* spp. serological reagents are devices that consist of antigens and antisera used in various serological tests to identify *Aspergillus* spp. antibodies in a patient's serum. The identification aids in the diagnosis of aspergillosis caused by fungi belonging to the genus *Aspergillus.* Aspergillosis is a disease marked by inflammatory granulomatous (tumor-like) lesions in the skin, ear, eyeball cavity, nasal sinuses, lungs, and occasionally the bones.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before

June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 6, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11767 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2145]

Medical Devices; Classification of "Blastomyces Dermatitidis" Serological Reagents

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Blastomyces dermatitidis* serological reagents into class II (performance standards). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of *Blastomyces dermatitidis* serological reagents:

1. Identification: *Blastomyces dermatitidis* serological reagents are devices that consist of antigens and antisera used in serological tests to identify the antibodies to *Blastomyces dermatitidis* in a patient's serum. The identification aids in the diagnosis of blastomycosis caused by the fungus *Blastomyces dermatitidis.* Blastomycosis is a chronic granulomatous (tumor-like) disease, which may be limited to the skin or lung or may be widely disseminated in the body resulting in lesions of the bones, liver, spleen, and kidneys.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that *blastomyces dermatitidis* serological reagents be classified into class II because there is a need for a performance standard that prescribes for these devices acceptable ranges of titer, sensitivity, and specificity and thereby minimizes the possibility that the devices may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel believes that general controls would not provide sufficient control over the devices' titer, sensitivity, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the devices and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and upon a review of the literature (Ref. 1). The Panels' review of the literature disclosed appreciable variation in the manufacture of these reagents with respect to their sensitivity, specificity, and titer. The Panel is aware of the availability of reference materials, performance specifications, and evaluation methods for these reagents.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of blastomycosis.

Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that *Blastomyces dermatitidis* serological reagents be classified into class II (performance standards). The agency believes that a performance standard is necessary for the device because general controls alone are insufficient to control the risks to health presented by this device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. "Specifications and Evaluation Methods for Immunological and Microbiological Reagents," Volume 1, 4th Ed., Center for Disease Control, Public Health Service, Department of Health, Education, and Welfare, C–4–7, 1975.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3060, to read as follows:

§ 866.3060 Blastomyces dermatitidis serological reagents.

(a) *Identification. Blastomyces dermatitidis* serological reagents are devices that consist of antigens and antisera used in serological tests to identify the antibodies to *Blastomyces dermatitidis* in a patient's serum. The identification aids in the diagnosis of blastomycosis caused by the fungus *Blastomyces dermatitidis.* Blastomycosis is a chronic granulomatous (tumor-like) disease, which may be limited to the skin or lung or may be widely disseminated in the body resulting in lesions of the bones, liver, spleen, and kidneys.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-11768 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 866

[Docket No. 78N-2146]

Medical Devices; Classification of "Bordetella" spp. Serological Reagents

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Bordetella* spp. serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of *Bordetella* spp. serological reagents:

1. Identification: *Bordetella* spp. serological reagents are devices that consist of antigens and antisera, including antisera conjugated with a fluorescent dye, used in serological tests to identify *Bordetella* spp. from cultured isolates and/or directly from clinical specimens. The identification aids in the diagnosis of diseases caused by bacteria belonging to the genus *Bordetella* and provides epidemiological information on these diseases. *Bordetella* spp. cause whooping cough and other similarly contagious and acute respiratory infections characterized by pneumonitis (inflammation of the lungs).

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that *Bordetella* spp. serological reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel has noted variation in the manufacture of these reagents regarding their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedure can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and on history of satisfactory performance of the devices.

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the devices to perform satisfactorily may lead to an error in the diagnosis of diseases caused by *Bordetella* ssp. infection. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of *Bordetella* ssp. may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that *Bordetella* spp. serological reagents be classified into class I (general controls) with no exemptions. The agency believes that these controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device..

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3065, to read as follows:

§ 866.3065 Bordetella spp. serological reagents.

(a) *Identification. Bordetella* spp. serological reagents are devices that consist of antigens and antisera, including antisera conjugated with a fluorescent dye, used in serological tests to identify *Bordetella* spp. from cultured isolates and/or directly from clincial specimens. The identification aids in the diagnosis of diseases caused by bacteria belonging to the genus *Bordetella* and provides epidemiological information on these diseases. *Bordetella* spp. cause whooping cough and other similarly contagious and acute respiratory infections characterized by pneumonitis (inflammation of the lungs).

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing clerk (HFA-305), Food and Drug Administration, Rm 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments are to be submitted, except that individuals may submit one copy. Comments, are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 6, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-11769 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 866

[Docket No. 78N-2147]

Medical Devices; Classification of "Brucella" spp. Serological Reagents

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Brucella* spp. serological reagents into class II (performance standards). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that these devices be classified into class II with the exception of *Brucella* spp. immunofluorescent reagents which the Panel recommended be classified into class I (general controls). The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all

devices. The effect of classifying a device into class II is to provide for future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of *Brucella* spp. serological reagents:

1. Identification: *Brucella* spp. serological reagents are devices that consist of antigens and antisera used for serological identification of *Brucella* spp. from cultured isolates derived from clinical specimens or to identify *Brucella* spp. antibodies in a patient's serum. Additionally, some of these reagents consist of antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify *Brucella* spp. directly from clinical specimens and/or cultured isolates derived from clinical specimens. The identification aids in the diagnosis and treatment of brucellosis (e.g., undulant fever, Malta fever) caused by bacteria belonging to the genus *Brucella* and provides epidemiological information on diseases caused by these microorganisms.

2. Recommended classification: The Microbiology Device Classification Panel recommends that *Brucella* spp. serological reagents (excluding immunofluorescent reagents) be classified into class II (performance standards) and that establishing a performance standard for this device be a medium priority. The Panel also recommends that *Brucella* spp. immunofluorescent reagents be classified into class I (general controls) and that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that *Brucella* spp. serological reagents (excluding immunofluorescent reagents) be classified into class II because there is a need for a performance standard that prescribes for these devices acceptable ranges of titer, sensitivity, and specificity and thereby minimizes the possibility that the devices may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Brucellosis is characterized by an acute blood infection phase followed by a chronic stage which may extend over many years and may involve many tissues but primarily the reticuloendothelial system (liver, spleen, bone marrow, etc.). Serodiagnosis of brucellosis may be necessary when isolation of the infecting microorganism is not possible. A marked rise in *Brucella* agglutinins (antibodies) in a patient's serum is presumptive evidence of brucellosis. Positive agglutination tests using isolated colonies may also be presumptive evidence of brucellosis. Patients with chronic brucellosis will often have negative culture results for the microorganisms but will demonstrate a marked rise of *Brucella* spp. antibody in the serum. The patient's serum is tested against *Brucella* spp. serological reagents which are commercially available. These commercial antigens provide variable results (Ref. 1). Unpublished data from the Center for Disease Control (CDC) for calendar years 1971 through 1975 demonstrate the variability of these reagents intended to meet CDC specifications (Ref. 2). The clinical experience of the Panel members and their familiarity with the literature have disclosed appreciable variation in the manufacture of *Brucella* spp. serological reagents (excluding immunofluorescent reagents) regarding their sensitivity, specificity, and titer. The Panel is aware of the availability of reference materials, performance specifications, and evaluation methods for the reagents (Ref. 3). The Panel believes that general controls would not provide sufficient control over the devices' titer, sensitivity, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the devices and that there is sufficient information to establish a standard. The Panel further recommends that *Brucella* spp. immunofluorescent reagents be classified into class I because the Panel believes general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel members noted variation in the manufacture of these reagents regarding their sensitivity, specificity, and titer. The Panel believes, however, that any variation in the sensitivity, specificity, and titer of these reagents resulting from manufacturing procedures can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and upon a review of the literature (Refs. 1, 2, and 3).

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of brucellosis. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of *Brucella* spp. may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

Proposed Classification

FDA agrees with the Panel recommendation with respect to *Brucella* spp. serological reagents (excluding immunofluorescent reagents) and is proposing that the device be classified into class II.

However, FDA disagrees with the Panel recommendation with respect to *Brucella* spp. immunofluorescent reagents and is proposing that the device be classified into class II (performance standards). The agency has reviewed the Panel recommendation to classify these devices into class I and has sought additional data and documentation on the safety and effectiveness of these devices. The agency has reviewed the available literature pertaining to immunofluorescent reagents. The agency recognizes that the performance characteristics of immunofluorescent reagents depend appreciably on how they are manufactured. The agency notes that immunofluorescent reagents are produced using essentially the same manufacturing procedures as those for the other serological reagents described herein. Therefore, the agency is also proposing that *Brucella* spp. immunofluorescent reagents be classified into class II (performance standards).

The agency believes that performance standards are necessary for the devices because general controls alone are insufficient to control the risks to health presented by the devices. A performance standard would provide reasonable assurance of the safety and effectiveness of the devices. The agency believes that there is sufficient information to establish standards to provide reasonable assurance of the safety and effectiveness of these devices.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Hansler, W. J., Jr. and F. P. Koontz, "Brucella," in "Manual of Clinical

Microbiology," 2d Ed., Edited by Lennette, E. H., E. H. Spaulding, and J. P. Truant, *American Society for Microbiology*, Washington, DC, pp. 295–301, 1974.

2. Results of a Five Year (1971–1975) Premarket Evaluation Program for Commercial Microbiological Diagnostic Products, Center for Disease Control, Public Health Service, Department of Health, Education, and Welfare, (unpublished).

3. "Specifications and Evaluation Methods for Immunological and Microbiological Reagents, Volume 1," 4th Ed., Center for Disease Control, Public Health Service, Department of Health, Education, and Welfare B1–5–7, 1975.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3085, to read as follows:

§ 866.3085 Brucella spp. serological reagents.

(a) *Identification. Brucella* spp. serological reagents are devices that consist of antigens and antisera used for serological identification of *Brucella* spp. from cultured isolates derived from clincial specimens of to identify *Brucella* spp. antibodies in a patient's serum. Additionally, some of these reagents consist of antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify *Brucella* spp. directly from clincial specimens and/or cultured isolates derived from clincial specimens. The identification aids in the diagnosis of brucellosis (e.g., undulant fever, Malta fever) casused by bacteria belonging to the genus *Brucella* and provides epidemiological information on disease caused by these microorganisms.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11770 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2149]

Medical Devices; Classification of "Campylobacter Fetus" Serological Reagents

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Campylobacter fetus* serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of *Campylobacter fetus* serological reagents:

1. Identification: *Campylobacter fetus* serological reagents are devices that consist of antisera conjugated with a fluorescent dye used to identify *Campylobacter fetus* from clinical specimens and/or cultured isolates dervied from clinical specimens. The identification aids in the diagnosis of disease caused by this bacterium belonging to the genus *Campylobacter* and provides epidemiological information on diseases caused by this micoorganism. *Campylobacter fetus* is a frequent cause of abortion in sheep and cattle and sometimes responsible for endocarditis (inflammation of certain membranes of the heart) and enteritis (inflammation of the intestines) in humans.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that *Campylobacter fetus* serological reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurances of the safety and effectiveness of these devices. The Panel has noted variation in the manufacture of these reagents as to their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedure can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and on a history of satisfactory performance of the devices.

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the devices to perform satisfactorily may lead to an error in the diagnosis of diseases caused by *Campylobacter fetus*. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of *Campylobacter fetus* may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination infection to other individuals or communities.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that *Campylobacter fetus*. serological reagents be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1). The Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3110, to read as follows:

§ 866.3110 Campylobacter fetus immunofluorescent reagents.

(a) *Identification. Campylobacter fetus* serological reagents are devices that consists of antisera conjugated with a fluorescent dye used to identify *Campylobacter fetus* from clinical specimens and/or cultured isolates derived from clinical specimens. The identification aids in the diagnosis of disease caused by this bacterium belonging to the genus *Campylobacter* and provides epidemiological information on diseases caused by this microorganism. *Campylobacter fetus* is a frequent cause of abortion in sheep and cattle and sometimes responsible for endocarditis (inflammation of certain membranes of the heart) and enteritis (inflammation of the intestines) in humans.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 6, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11771 Filed 4–21–80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 866

[Docket No. 78N–2150]

Medical Devices; Classification of Chlamydia Serological Reagents

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and drug Administration (FDA) is issuing for public comment a proposed regulation classifying chlamydia serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of chlamydia serological reagents:

1. Identification: Chlamydia serological reagents are devices that consist of antigens and antisera used in serological tests to identify chlamydial antibodies in a patient's serum. Additionally, some of these reagents consist of chlamydia antisera conjugated with a fluorescent dye, and are used to identify chlamydia directly from clinical specimens and/or cultured isolates derived from clinical specimens. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus *Chlamydia* and provides epidemiological information on diseases caused by these microorganisms. Chlamydia are the causative agents of psittacosis (a form of pneumonia), lymphogranuloma venereum (a venereal disease), and trachoma (a chronic disease of the eye and eyelid).

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that chlamydia serological reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel has noted variation in the manufacture of these reagents as to their sensitivity, specificity, and titer. The Panel believes however, that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedure can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and on a history of satisfactory performance of the device.

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of disease caused by chlamydia. In appropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of chlamydia may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that chlamydiae serological reagents be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3120, to read as follows:

§ 866.3120 Chlamydia serological reagents.

(a) *Identification.* Chlamydia serological reagents are devices that consist of antigens and antisera used in serological tests to identify chlamydial antibodies in a patient's serum. Additionally, some of these reagents consist of chlamydia antisera conjugated with a fluorescent dye and are used to identify chlamydia directly from clinical specimens and/or cultured isolates derived from clinical specimens. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus *Chlamydia* and provides epidemiological information on diseases caused by these microorganisms. Chlamydia are the causative agents of psittacosis (a form of pneumonia), lymphogranuloma venereum (a venereal disease), and trachoma (a chronic disease of the eye and eyelid).

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four

copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 6, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-11772 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 866

[Docket No. 78N-2151]

Medical Devices; Classification of "Citrobacter" spp. Serological Reagents

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Citrobacter* spp. serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of *Citrobacter* spp. serological reagents:

1. Identification: *Citrobacter* spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Citrobacter* spp. from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus *Citrobacter* and provides epidemiological information on diseases caused by these microorganisms. *Citrobacter* spp. have occasionally been associated with urinary tract infections.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that *Citrobacter* spp. serological reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel members have noted variation in the manufacture of these reagents regarding their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedure can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and on a history of satisfactory performance of the devices.

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the devices to perform satisfactorily may lead to an error in the diagnosis of diseases caused by *Citrobacter* spp. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of *Citrobacter* spp. may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that *Citrobacter* spp. serological reagents be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3125, to read as follows:

§ 866.3125 Citrobacter spp. serological reagent.

(a) *Identification. Citrobacter* spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Citrobacter* spp. from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus *Citrobacter* and provides epidemiological information on diseases caused by these microorganisms. *Citrobacter* spp. have occasionally been associated with urinary tract infections.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 6, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-11773 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 866

[Docket No. 78N-2152]

Medical Devices; Classification of "Coccidioides Immitis" Serological Reagents

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Coccidioides immitis* serological reagents into class II (performance standards). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being

taken under the Medical Device Amendments of 1976.

DATE: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of *Coccidioides immitis* serological reagents:

1. Identification: *Coccidioides immitis* serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Coccidioides immitis* antibodies in a patient's serum. The identification aids in the diagnosis of coccidioidomycosis caused by a fungus belonging to the genus *Coccidioides* and provides epidemiological information on diseases caused by this microorganism. An infection with *Coccidioides immitis* produces symptoms varying in severity from those accompanying the common cold to those of influenza.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that *Coccidioides immitis* serological reagents be classified into class II because there is a need for a performance standard that prescribes for these devices acceptable ranges of titer, sensitivity, and specificity and thereby minimizes the possibility that the devices may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Because the diagnosis of coccidioidomycosis cannot always be confirmed by cultural isolation of the infecting organism or by histological examination, serological testing often provides the only rapid, though presumptive, evidence of infection. The clinical experience of the Panel revealed appreciable variation in the manufacture of these reagents as to their sensitivity, specificity, and titer. The Panel is aware of the availability of reference materials, performance specifications and evaluation methods for these reagents (Ref. 1). The Panel believes that general controls would not provide sufficient control over the devices' titer, sensitivity, and specificity. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the devices and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and upon a review of the literature (Ref. 1).

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of coccidioidomycosis. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of *Coccidioides immitis* antibodies may contribute to epidemiological misinformation. Consequently, the risk of incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that *Coccidioides immitis* serological reagents be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons from 9 a.m. to 4 p.m., Monday through Friday.

1. "Specificationa and Evaluation Methods for Immunological and Microbiological Reagents," Vol. 1, 4th Ed., Center for Disease Control, Public Health Service, Department of Health, Education, and Welfare, C–8–10, 1975.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3135, to read as follows:

§ 866.3135 Coccidioides immitis serological reagents.

(a) *Identification. Coccidioides immitis* serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Coccioides immitis* antibodies in a patient's serum. The identification aids in the diagnosis of coccidioidomycosis caused by a fungus belonging to the genus *Coccidioides* and provides epidemiological information on disease caused by this microorganism. An infection with *Coccidioides immitis* produces symptoms varying in severity from those accompanying the common cold to those of influenza.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 6, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11774 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2153]

Medical Devices; Classification of "Corynebacterium" spp. Serological Reagents

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Corynebacterium* spp. serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These

actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panal, an FDA advisory committee, made the following recommendation regarding the classification of *Corynebacterium* spp. serological reagents:

1. Identification: *Corynebacterium* spp. serological reagents are devices that consist of antisera conjugated with a fluorescent dye used to identify *Corynebacterium* spp from clinical specimens. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus *Corynebacterium* and provides epidemiological information on diseases caused by these microorganisms. The principal human pathogen of this genus *Corynebacterium diphtheriae,* causes diphtheria. However, many other types of corynebacteria form part of the normal flora of the human respiratory tract, other mucus membranes, and skin and are either nonpathogenic or have an uncertain pathogenic role.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that *Corynebacterium* spp. serological reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel members have noted variation in the manufacture of these reagents regarding their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedure can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and on a history of satisfactory performance of the devices.

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of diseases caused by *Corynebacterium* spp., principally human diphtheria. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of *Corynebacterium* spp. may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that *Corynebacterium* spp. serological reagents be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3140, to read as follows:

§866.3140 Corynebacterium spp. serological reagents.

(a) *Identification. Corynebacterium* spp. serological reagents are devices that consist of antisera conjugated with a fluorescent dye used to identify *Corynebacterium* spp. from clinical specimens. The identification aids in the diagnosis of disease cause by bacteria belonging to the genus *Corynebacterium* and provides epidemiological information on diseases caused by these microorganisms. The principal human pathogen of this genus *Corynebacterium diphtheriae,* causes diphtheria. However, many other types of corynebacteria form part of the normal flora of the human respiratory tract, other mucus membranes, and skin and are either nonpathogenic or have an uncertain role.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours or 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 6, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11775 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2154]

Medical Devices; Classification of Coxsackievirus Serological Reagents

AGENCY: Food and Drug Administation.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying coxsackievirus serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to required that the the device meet only general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written coments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulations. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the

classification of coxsackievirus serological reagents:

1. Identification: Coxsackievirus serological reagents are devices that consist of antigens and antisera used in serological tests to identify coxsackievirus antibodies in a patient's serum. Additionally, some of these reagents consists of coxsackievirus antisera conjugated with a fluorescent dye, that are used to identify coxsackievirus from clinical specimens and/or from tissue culture isolates derived from clinical specimens. The identification aids in the diagnosis of coxsackievirus infections and provides epidemiological information on diseases caused by these viruses. Coxsackieviruses produce a variety of infections, including common colds, meningitis (inflammation of brain and spinal cord membranes), herpangina (brief fever accompanied by ulcerated lesions of the throat) and myopericarditis (inflammation of heart tissue).

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that coxsackievirus serological reagents be classified class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel notes that a definitive diagnosis of coxsackievirus infection by serological methods is often retrospective since the patient generally recovers (or succumbs) from the illness before the serodiagnosis can be made. The Panel also notes that there is currently no specific treatment for disease caused by coxsackieviruses (i.e., there is a lack of available antiviral drug therapy). Consequently, the risk of an incorrect diagnosis relates primarily to the dissemmination of infection to other individuals or communities. The Panel members have noted variation in the manufacture of these reagents as to their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedure can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulations.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and on a history of satisfactory performance of the devices.

5. Risks to health: Epidemiological misinformation: Failure of the devices to detect the presence of coxsackieviruses may contribute to epidemiological misinformation. Consquently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that coxsackievirus seriological reagents be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3145, to read as follows:

§ 866.3145 Coxsackievirus serological reagents.

(a) *Identification.* Coxsackievirus serological reagents are devices that consist of antigens and antisera used in serological tests to identify coxsackievirus antibodies in a patient's serum. Additonally, some of these reagents consist of coxsackievirus antisera conjugated with a fluorescent dye, that are used to identify coxsackievirus from clinical specimens and/or from tissue culture isolates derived from clinical specimens. The identification aids in the diagnosis of coxsackievirus infections and provides epidemiological information on diseases caused by these viruses. Coxsackieviruses produce a variety of infections, including common colds, meningitis (inflammation of brain and spinal cord membranes), herpangina (brief fever accompanied by ulcerated lesions of the throat), and myopericarditis (inflammation of heart tissue).

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 6, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11776 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

21 CFR Part 866

[Docket No. 78N–2156]

Medical Devices; Classification of "Cryptococcus Neoformans" Serological Reagents

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Cryptococcus neoformans* serological reagents into class II (performance standards). The FDA is also publishing the recommendation of the Microbiology Device Classification Panel that these devices be classified into class II with the exception of *Cryptococcus neoformans* immunofluorescent reagents which the Panel recommended be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. The effect of classifying a device into class II is to provide for future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of *Cryptococcus neoformans* serological reagents:

1. Identification: *Cryptococcus neoformans* serological reagents are devices that consist

of antigens and antisera used in serological tests to identify *Cryptococcus neoformans* antibodies in a patient's serum. Additionally, some of these reagents consist of antisera conjugated with a fluorescent dye (immunofluorescent reagents) and are used to identify *Cryptococcus neoformans* directly from clinical specimens and/or from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of *Cryptococcosis* and provides epidemiological information on this type of disease. Cryptococcosis infections are found most often as chronic meningitis (inflammation of brain membranes) and, if not treated, are usually fatal.

2. Recommended classification: The Microbiology Device Classification Panel recommends that *Cryptococcus neoformans* serological reagents (excluding immunofluorescent reagents) be classified into class II (performance standards) and that establishing a performance standard for this device be a high priority. The Panel also recommends that *Cryptococcus neoformans* immunofluorescent reagents be classified into class I (general controls) and that there be no exemptions.

3. Summary of reasons for recommendations: The Panel recommends that *Cryptococcus neoformans* serological reagents (excluding immunofluorescent reagents) be classified into class II because there is a need for a performance standard that prescribes for these devices acceptable ranges of titer, sensitivity, and specificity and thereby minimizes the possibility that the devices may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel notes that because of the serious nature of cryptococcosis, rapid diagnosis and treatment is necessary. Serological tests are often used for the diagnosis of this disease. Kaufman, et al. tested 24 commercial latex agglutination test kits (kits which utilize antigen coated latex suspensions from a single manufacturer). Fourteen kits were found unsatisfactory (Ref. 1). The Panel believes that general controls would not provide sufficient control over the device's titer, sensitivity, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard. The clinical experience of the Panel members and their familiarity with the literature has disclosed appreciable variation in the manufacture of *Cryptococcus neoformans* serological reagents (excluding immunofluorescent reagents) with respect to their sensitivity, specificity, and titer. The Panel is aware of the ability of reference materials, performance specifications, and evaluation methods for these reagents (Ref. 2). The Panel further recommends that *Cryptococcus neoformans* immunofluorescent reagents be classified into class I because the Panel believes general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel members noted variation in the manufacture of these reagents with respect to their sensitivity, specificity, and titer. The Panel believes, however, that any variation in their sensitivity, specificity, and titer resulting from manufacturing procedures can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1–3).

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of Cryptococcosis. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of *Cryptococcus neoformans* may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

Proposed Classification

FDA agrees with the Panel recommendation with respect to *Cryptococcus neoformans* serological reagents (excluding immunofluorescent reagents) and is proposing that the devices be classified into class II (performance standards). However, FDA disagrees with the Panel recommendation with respect to *Cryptococcus neoformans* immunofluorescent reagents and is proposing that these immunofluorescent reagents be classified into class II (performance standards). The agency has reviewed the Panel recommendation to classify immunofluorescent reagents into class I (general controls) and has sought additional data and documentation on the safety and effectiveness of these devices. The agency has reviewed the available literature pertaining to immunofluorescent reagents. The agency recognizes that the performance characteristics of antigens and immunofluorescent reagents depends appreciably upon how they are manufactured. The agency notes immunofluorescent reagents are produced using essentially the same manufacturing procedures as those for the other serological reagents described herein. The agency also is aware of the availability of reference materials, performance specifications, and evaluation methods for these reagents (Ref. 2). Therefore, the agency is proposing that *Cryptococcus neoformans* immunofluorescent reagents be classified into class II (performance standards).

The agency believes that performance standards are necessary for *Cryptococcus neoformans* serological reagents because general controls alone are insufficient to control the risks to health presented by these devices. Performance standards would provide reasonable assurance of the safety and effectiveness of the devices. The agency believes that there is sufficient information to establish standards to provide reasonable assurance of the safety and effectiveness of these devices.

References

The following information has been placed in the Office of the Hearing Clerk (HFA–305), Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, and may be viewed by interested persons from 9 a.m. to 4 p.m. Monday through Friday.

1. Kaufman, L., G. Cowart, S. Blumer, A. Stine, and R. Wood, "Evaluation of a Commercial Latex Agglutination Test Kit for Cryptococcal Antigen," *Applied Microbiology*, 27(3):620–621, 1974.

2. "Specifications and Evaluation Methods for Immunological and Microbiological Reagents, Volume I, 4th Ed.," Center for Disease Control, Public Health Service, Department of Health, Education, and Welfare, C–11–14, 1975.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3165 as follows:

§ 866.3165 Cryptococcus neoformans serological reagents.

(a) *Identification. Cryptococcus neoformans* serological reagents are devices that consist of antigens and antisera used in serological tests used to identify *Cryptococcus neoformans* antibodies in a patient's serum. Additionally, some of these reagents consist of antisera conjugated with a fluorescent dye (immunofluorescent reagents) and are used to identify *Cryptococcus neoformans* directly from clinical specimens and/or from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of Cryptococcosis and provides epidemiological information on this type of disease. Cryptococcosis infections are found most often as chronic meningitis (inflammation of brain membranes) and, if not treated, are usually fatal.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written

comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 6, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-11777 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 866

[Docket No. 78N-2157]

Medical Devices; Classification of Cytomegalovirus Serological Reagents

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying cytomegalovirus serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of cytomegalovirus serological reagents:

1. Identification: Cytomegalovirus serological reagents are devices that consist of antigens and antisera used in serological tests to identify cytomegalovirus antibodies in a patient's serum. The identification aids in the diagnosis of diseases caused by cytomegaloviruses (principally cytomegalic inclusion disease) and provides epidemiological information on these diseases. Cytomegalic inclusion disease is a generalized infection of infants and is caused by intrauterine or early postnatal infection with the virus. The disease may cause severe congenital abnormalities, such as microcephaly (abnormal smallness of the head), motor disability, and mental retardation. Cytomegalovirus infection has also been associated with acquired hemolytic anemia, acute and chronic hepatitis, and an infectious mononucleosis-like syndrome.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that cytomegalovirus serological reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel recognizes that a definitive diagnosis of cytomegalovirus infection by serological methods is often retrospective since the patient generally recovers (or succumbs) from the illness before the serodiagnosis can be made. The Panel also notes that there is currently no specific treatment for these diseases (i.e., there is a lack of available antiviral drug therapy). Consequently, the risk of an incorrect diagnosis relates primarily to the dissemination of infection to other individuals or communities. The Panel has noted variation in the manufacture of these reagents regarding their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity, and titer that results from manufacturing procedures can be adequately controlled by manufacturer compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members personal knowledge of, and clinical experience with, the devices and on a history of satisfactory performance of these devices.

5. Risks to health: Epidemiological misinformation: Failure of the device to detect the presence of cytomegaloviruses may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates primarily to the dissemination of infection to other individuals or communities.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that cytomegalovirus serological reagents be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3175, to read as follows:

§ 866.3175 Cytomegalovirus serological reagents.

(a) *Identification.* Cytomegalovirus serological reagents are devices that consist of antigens used in serological tests to identify cytomegalovirus antibodies in a patient's serum. The identification aids in the diagnosis of diseases caused by cytomegaloviruses (principally cytomegalic inclusion disease) and provides epidemiological information on these diseases. Cytomegalic inclusion disease is a generalized infection of infants and is caused by intrauterine or early postnatal infection with the virus. The disease may cause severe congenital abnormalities, such as microcephaly (abnormal smallness of the head), motor disability, and mental retardation. Cytomegalovirus infection has also been associated with acquired hemolytic anemia, acute and chronic hepatitus, and an infectious mononucleosis-like syndrome.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 6, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-11778 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 866

[Docket No. 78N-2158]

Medical Devices; Classification of Echinococcus spp. Serological Reagents

AGENCY: Food and Drug Administration.

ACTION: Proposed rule

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Echinococcus* spp. serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health, Education, and Welfare 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of *Echinococcus* spp. serological reagents:

1. Identification: *Echinococcus* spp. serological reagents are devices that consist of *Echinococcus* spp. antigens and antisera used in serological tests to identify *Echinococcus* spp. antibodies in a patient's serum. The identification aids in the diagnosis of echinococcosis, caused by parasitic tapeworms belonging to the genus *Echinococcus* and provides epidemiological information on this type of disease. Echinococcosis is characterized by the development of cysts in the liver, lung, kidneys, and other organs formed by the larva of the infecting organism.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that *Echinococcus* spp. serological reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. Serodiagnosis is most often the method of choice for identifying *Echinococcus* spp. infection.

The Panel has noted variation in the manufacture of these reagents regarding their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagents sensitivity, specificity, and titer that results from manufacturing procedures can be adequately controlled by manufacturer's compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and on a history of satisfactory performance of the devices.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of these devices to perform satisfactorily may lead to anerror in the diagnosis of echinococcosis or may contribute to epidemiological misinformation. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that *Echinococcus* spp. serological reagents be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3200, to read as follows:

§ 866.3200 Echinococcus spp. serological reagents.

(a) *Identification. Echinococcus* spp. serological reagents are devices that consist of *Echinococcus* spp. antigens and antisera used in serological tests to identify *echinococcus* spp. antibodies in a patient's serum. The identification aids in the diagnosis of echinococcosis, caused by parasitic tapeworms belonging to the genus *Echinococcus* and provides epidemiological information of this type of disease. Echinococcosis is characterized by the development of cysts in the liver, lung, kidneys, and other organs formed by the larva of the infecting organism.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments shall be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 6, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-11779 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 866

[Docket No. 78N-2159]

Medical Devices; Classification of Echovirus Serological Reagents

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying echovirus serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health,

Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of echovirus serological reagents:

1. Identification: Echovirus serological reagents are devices that consist of antigens and antisera used in serological tests to identify echovirus antibodies in a patient's serum. Additionally, some of these reagents consist of echovirus antisera conjugated with a fluorescent dye used to identify echoviruses from clinical specimens and/or from tissue culture isolates derived from clinical specimens. The identification aids in the diagnosis of echovirus infections and provides epidemiological information on diseases caused by these viruses. Echoviruses cause illnesses such as meningitis (inflammation of the brain and spinal cord membranes), febrile illnesses (accompanied by fever) with or without rash, and the common cold.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that echovirus serological reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel notes that a definitive diagnosis of echovirus infection by serological methods is often retrospective since the patient generally recovers (or succumbs) from the illness before the serodiagnosis can be made. The Panel also notes that there is currently no specific treatment for these diseases (i.e., there is a lack of available antiviral drug therapy). Consequently, the risk of an incorrect diagnosis relates primarily to the dissemination of infection to other individuals or communities. The Panel has noted variation in the manufacture of these reagents regarding their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedures can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices, and on a history of satisfactory performance of the devices.

5. Risks to health: Epidemiological misinformation: Failure of the device to detect the presence of echoviruses may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates primarily to the dissemination of infection to other individuals or communities.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that echovirus serological reagents be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3205, to read as follows:

§ 866.3205 Echovirus serological reagents.

(a) *Identification:* Echovirus serological reagents are devices that consist of antigens and antisera used in serological tests to identify echovirus antibodies in a patient's serum. Additionally, some of these reagents consist of echovirus antisera conjugated with a fluorescent dye used to identify echoviruses from clinical specimens and/or from tissue culture isolates derived from clinical specimens. The identification aids in the diagnosis of echovirus infections and provides epidemiological information on diseases caused by these viruses. Echoviruses cause illnesses such as meningitis (inflammation of the brain and spinal cord membranes), febrile illnesses (accompanied by fever) with or without rash, and the common cold.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 6, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11780 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2160]

Medical Devices; Classification of Entamoeba Histolytica Serological Reagents

AGENCY: Food and Drug Administration.

ACTION: Proposed rules.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Entamoeba histolytica* serological reagents into class II (performance standards). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that these devices be classified into class II with the exception of *Entamoeba histolytica* immunofluorescent reagents, which the Panel recommended be classified into class I (general controls). The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. The effect of classifying a device into class II is to provide for future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440) Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the

development of the proposed regulation. The Microbiology Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of *Entamoeba histolytica* serological reagents:

1. Identification: *Entamoeba histolytica* serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Entamoeba histolytica*, antibodies in a patient's serum. Additionally, some of these reagents consist of antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify *Entamoeba histolytica* directly from clinical specimens. The identification aids in the diagnosis of amebiasis caused by the microscopic protozoan parasite *Entamoeba histolytica* and provides epidemiological information on diseases caused by this parasite. The parasite may invade the skin, liver, intestines, lungs, and diaphragm, causing disease conditions such as indolent ulcers, an amebic hepatitis, amebic dysentery, and pulmonary lesions.

2. Recommended classification: The Microbiology Device Classification Panel recommends that *Entamoeba histolytica* serological reagents (excluding immunofluorescent reagents) be classified into class II (performance standards) and that establishing a performance standard for the device be a medium priority. The Panel also recommends that *Entamoeba histolytica* immunofluorescent reagents be classified into class I (general controls) and that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that *Entamoeba histolytica* serological reagents (excluding immunofluorescent reagents) be classified into class II because there is a need for a performance standard that prescribes for these devices acceptable ranges of titer, sensitivity, and specificity and thereby minimizes the possibility that the devices may generate inaccurate diagnostic information.

Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Serological tests are useful in making a diagnosis when disease involving amebiasis and infections by other tissue-inhabiting parasites occur (Ref. 1). The Panel believes that general controls would not provide sufficient control over the devices' titer, sensitivity, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the devices and that there is sufficient information to establish a standard. The clinical experience of the Panel members and their familiarity with the literature has disclosed appreciable variation in the manufacture of these reagents regarding their sensitivity, specificity, and titer (Ref. 1).

The Panel further recommends that *Entamoeba histolytica* immunofluorescent reagents be classified into class I because the Panel believes general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel members noted variation in the manufacture of these reagents regarding the reagents' sensitivity, specificity, and titer. The Panel believes, however, that any variation in the sensitivity, specificity, and titer of these reagents resulting from manufacturing procedures can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and upon a review of the literature (Refs. 1 through 3).

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of disease caused by *Entamoeba histolytica*. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of *Entamoeba histolytica* may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

Proposed Classification

FDA agrees with the Panel recommendations with respect to *Entamoeba histolytica* serological reagents (excluding immunofluorescent reagents) and is proposing that these devices be classified into class II (performance standards). However, FDA disagrees with the Panel recommendation with respect to *Entamoeba histolytica* immunofluorescent reagents and is proposing that these devices be classified into class II (performance standards). The agency has reviewed the Panel recommendation to classify this device into class I (general controls) and has obtained additional data and documentation on the safety and effectiveness of these devices. The agency has reviewed the available literature pertaining to immunofluorescent reagents. The agency recognizes that the performance characteristics of immunofluorescent reagents depend appreciably upon how they are manufactured. The agency notes that immunofluorescent reagents are produced using essentially the same manufacturing procedures as those for the other serological reagents described herein. Therefore, the agency is proposing that *Entamoeba histolytica* immunofluorescent reagents be classified into class II (performance standards).

The agency believes that performance standards are necessary for *Entamoeba histolytica* serological reagents because general controls alone are insufficient to control the risks to health presented by these devices. Performance standards would provide reasonable assurance of the safety and effectiveness of the devices. The agency believes that there is sufficient information to establish a performance standard for these devices.

References

The following information has been placed in the office of the Hearing Clerk (HFA–305) (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Swartzwelder, J. C., "Clinical Parasitology: Introduction and General Methods," *Manual of Clinical Microbiology*, 2d Ed., Edited by Lenette, E. H., E. H. Spaulding, and J. P. Truant, American Society for Microbiology, Washington, DC, pp. 577–581, 1974.

2. Results of a Five-Year (1971–1975) Premarket Evaluation Program for Commercial Microbiological Diagnostic Products, Center for Disease Control, Public Health Service, Department of Health, Education, and Welfare (unpublished).

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3220, to read as follows:

§ 866.3220 Entamoeba histolytica serological reagents.

(a) *Identification. Entamoeba histolytica* serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Entamoeba histolytica* antibodies in a patient's serum. Additionally, some of these reagents consist of antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify *Entamoeba histolytica* directly from clinical specimens. The identification aids in the diagnosis of amebiasis caused by the microscopic protozoan parasite *Entamoeba histolytica* and provides epidemiological information on diseases caused by this parasite. The parasite may invade the skin, liver, intestines, lungs, and diaphragm, causing disease conditions such as indolent ulcers, an amebic hepatitis, amebic dysentery, and pulmonary lesions.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be

submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 6, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-11781 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 866

[Docket No. 78N-2162]

Medical Devices; Classification of Epstein-Barr Virus Serological Reagents

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying Epstein-Barr virus serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of Epstein-Barr virus serological reagents:

1. Identification: Epstein-Barr virus serological reagents are devices that consist of antigens and antisera used in serological tests to identify Epstein-Barr virus antibodies in a patient's serum. The identification aids in the diagnosis of Epstein-Barr virus infectious and provides epidemiological information on diseases caused by this virus. Epstein-Barr virus is thought to cause the infections mononucleosis and has been associated with Burkitt's lymphoma (a tumor of the jaw in African children and young adults) and postnasal carcinoma (cancer).

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that Epstein-Barr virus serological reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel notes that a positive diagnosis of Epstein-Barr virus infection by serological methods is often retrospective since the patient generally recovers (or succumbs) from the illness before the serodiagnosis can be made. The Panel also notes that there is no specific treatment at this time for these diseases (i.e., there is a lack of available antiviral drug therapy). Consequently, the risk of an incorrect diagnosis relates primarily to the dissemination of infection to other individuals or communities. The Panel has noted variation in the manufacture of these reagents regarding their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedures can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and on a history of satisfactory performance of the devices.

5. Risks to health: Epidemiological misinformation: Failure of the device to detect the presence of Epstein-Barr virus may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates primarily to the dissemination of infection to other individuals or communities.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that Epstein-Barr virus serological reagents be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3235, to read as follows:

§ 866.3235 Epstein-Barr virus serological reagents.

(a) *Identification.* Epstein-Barr virus serological reagents are devices that consist of antigens and antisera used in serological tests to identify Epstein-Barr virus antibodies in a patient's serum. The identification aids in the diagnosis of Epstein-Barr virus infections and provides epidemiological information on diseases caused by this virus. Epstein-Barr virus is thought to cause infectious mononucelosis and has been associated with Burkitt's lymphoma (a tumor of the jaw in African children and young adults) and postnasal carcinoma (cancer).

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 6, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-11782 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 866

[Docket No. 78N-2163]

Medical Devices; Classification of Equine Encephalomyelitis Virus Serological Reagents

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying equine encephalomyelitis virus serological reagents into class I (general controls). FDA is also publishing the recomendation of the Microbiology Device Classification Panel that the device be classified into

class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Springs, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of equine encephalomyelitis virus serological reagents:

1. Identification: Equine encephalomyelitis virus serological reagents are devices that consist of antigens and antisera used in serological tests to identify equine encephalitis virus antibodies in a patient's serum. The identification aids in the diagnosis of diseases caused by equine encephalomyelitis viruses and provides epidemiological information on these viruses. Equine encephalomyelitis viruses are transmitted to humans by the bite of insects such as mosquitos and ticks and may cause encephalitis (inflammation of the brain), rash, acute arthritis, or hepatitis.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that equine encephalomyelitis virus serological reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel recognizes that diagnosis of diseases caused by equine encephalomyelitis viruses by serological methods is often retrospective since the patient generally recovers (or succumbs) from the illness before the serodiagnosis can be made. The Panel also notes that there is no specific treatment at this time for the disease(s) (i.e., there is a lack of available antiviral drug therapy). Consequently, the risk of incorrect diagnosis relates primarily to the dissemination of infection to other individuals or communities. The Panel members noted variation in the manufacture of these reagents regarding their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedure can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and on a history of satisfactory performance of the devices.

5. Risks to health: Epidemiological misinformation: Failure of the device to detect the presence of equine encephalomyelitis viruses may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates primarily to the dissemination of infection to other individuals or communities.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that equine encephalomyelitis virus serological reagents be classified into class I (general controls) with no exemptions because the agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3240, to read as follows:

§ 866.3240 Equine encephalomyelitis virus serological reagents.

(a) *Identification.* Equine encephalomyelitis virus serological reagents are devices that consist of antigens and antisera used in serological tests to identify equine encephalitis virus antibodies in a patient's serum. The identification aids in the diagnosis of diseases caused by equine encephalomyelitis viruses and provides epidemiological information on these viruses. Equine encephalomyelitis viruses are transmitted to humans by the bite of insects such as mosquitos and ticks and may cause encephalitis (inflammation of the brain), rash, acute arthritis, or hepatitis.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 6, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11783 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2164]

Medical Devices; Classification of Erysipelothrix Rhusiopathiae Serological Reagents

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Erysipelothrix rhusiopathiae* serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATE: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of *Erysipelothrix rhusiopathiae* serological reagents:

-1. Identification: *Erysipelothrix rhusiopathiae* serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Erysipelothrix rhusiopathiae* from cultured isolates derived from clinical speciments. The identification aids in the diagnosis of disease caused by this bacterium belonging to the genus *Erysipelothrix*. This organism is responsible for a variety of inflammation of the skin following skin abrasions from contact with fish, shellfish, or poultry.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that *Erysipelothrix rhusiopathiae* serological reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel members have noted variation in the manufacture of these reagents regarding their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivitry, specificity, and titer resulting from manufacturing procedures can be adequately controlled by manufacturers' compliance with lableing requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and on a history of satisfactory performance of the devices.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of disease caused by *Erysipelothrix rhusiopathiae*. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that *Erysipelothrix rhusiopathiae* serological reagents be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new §866.3250, to read as follows:

§ 866.3250 Erysipelothrix rhusiopathiae serological reagents.

(a) *Identification. Erysipelothrix rhusiopathiae* serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Erysipelothrix rhusiopathiae* from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of disease caused by this bacterium belonging to the genus *Erysipelothrix*. This organism is responsible for a variety of inflammations of the skin following skin abrasions from contact with fish, shellfish, or poultry.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments, are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 6, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11784 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2165]

Medical Devices; Classification of Escherichia Coli Serological Reagents

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Escherichia coli* serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of *Escherichia coli* serological reagents:

1. Identification: *Escherichia coli* serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Escherichia coli* from cultured isolates derived from clinical specimens. Additionally, some of these reagents consist of *Escherichia coli* antisera conjugated with a fluorescent dye used to identify *Escherichia coli* directly from clinical specimens and/or cultured isolates derived from clinical specimens. The identification aids in the diagnosis and treatment of disease caused by this bacterium belonging to the genus *Escherichia* and provides epidemiological information on diseases caused by this microorganism. Although *Escherichia coli* constitutes the greater part of the microorganisms found in the intestinal tract in humans and is usually nonpathogenic, those strains which are pathogenic may cause urinary tract infections and/or epidemic diarrheal disease, especially in children.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that *Escherichia coli* serological reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel members have noted variation in the manufacture of these reagents regarding their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedure can be adequately controlled by manufacturers'

compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and on a history of satisfactory performance of the devices.

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of disease caused by *Escherichia coli*. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of *Escherichia coli* may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that *Escherichia coli* serological reagents be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3255, to read as follows:

§ 866.3255 Escherichia coli serological reagents.

(a) *Identification. Escherichia coli* serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Escherichia coli* from cultured isolates derived from clinical specimens. Additionally, some of these reagents consist of *Escherichia coli* antisera conjugated with a fluorescent dye used to identify *Escherichia coli* directly from clinical specimens and/or cultured isolates derived from clinical specimens. The identification aids in the diagnosis and treatment of disease caused by this bacterium belonging to the genus *Escherichia* and provides epidemiological information on diseases caused by this microorganism. Although *Escherichia coli* constitutes the greater part of the microorganisms found in the intestinal tract in humans and is usually nonpathogenic, those strains which are pathogenic may cause urinary tract infections and/or epidemic diarrheal disease, especially in children.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 6, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11785 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2166]

Medical Devices; Classification of Flavobacterium spp. Serological Reagents

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Flavobacterium* spp. serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classificaton Panel, an FDA advisory committee, made the following recommendation regarding the classification of *Flavobacterium* spp. serological reagents:

1. Identification: *Flavobacterium* spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Flavobacterium* spp. from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus *Flavobacterium* and provides epidemiological information on diseases caused by these microorganisms. Most members of this genus are found in soil and water and, under certain conditions, may become pathogenic to humans. *Flavobacterium meningosepticum* is highly virulent for the newborn, in whom it may cause epidemics of septicemia (blood poisoning) and meningitis (inflammation of the membranes of the brain) and is usually attributable to contaminated hospital equipment.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that *Flavobacterium* spp. serological reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel has noted variation in the manufacture of these reagents regarding their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedure can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and on a history of satisfactory performance of the devices.

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of diseases caused by *Flavobacterium* spp. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of *Flavobacterium* spp. may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that

Flavobacterium spp. serological reagents be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3270, to read as follows:

§ 866.3270 Flavobacterium spp. serological reagents.

(a) *Identification. Flavobacterium* spp. serological reagents are devices that consist of antigents and antisera used in serological tests to identify *Flavobacterium* spp. from cultured isolates derived from clincial specimens. The identification aids in the diagnosis of disease caused by bacteria belinging to the genus *Flavobacterium* and provides epidemiological information on diseases caused by these microorganisms. Most members of this genus are found in soil and water and, under certain conditions, may become pathogenic to humans. *Flavobacterium meningosepticum* is highly virulent for the newborn, in whom it may cause epidemics of septicemia (blood poisoning) and menigitis (inflammation of the membranes of the brain) and is usually attributable to contaminated hospital equipment.

(b) *Classification.* Class I (general controls.)

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 6, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11786 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

21 CFR Part 866

[Docket No. 78N–2167]

Medical Devices; Classification of Francisella Tularensis Serological Reagents

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Francisella tularensis* serological reagents into class II (performance standards). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that these devices be classified into class II with the exception of *Francisella tularensis* immunofluorescent reagents, which the Panel recommended be classified into class I (general controls). The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. The effect of classifying a device into class II is to provide for future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of *Francisella tularensis* serological reagents:

1. Identification: *Francisella tularensis* serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Francisella tularensis* antibodies in a patient's serum and/or to identify *Francisella tularensis* in cultured isolates derived from clinical specimens. Additionally, some of these reagents consist of antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify *Francisella tularensis* directly from clinical specimens and/or cultured isolates derived from clinical specimens. The identification aids in the diagnosis of tularemia caused by *Francisella tularensis* and provides epidemiological information on this disease. Tularemia is a disease principally of rodents, but may be transmitted to humans through handling of infected animals, animal products, or by the bites of fleas and ticks. The disease takes on several forms depending upon the site of infection, such as skin lesions, lymph node enlargements, or pulmonary infection.

2. Recommended classification: The Microbiology Device Classification Panel recommends that *Francisella tularensis* serological reagents (excluding into class II (performance standards) and that establishing a performance standard for this device be a low priority. The Panel also recommends that *Francisella tularensis* immunofluorescent reagents be classified into class I (general controls) and that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that *Francisella tularensis* serological reagents (excluding immunofluorescent reagents) be classified into class II because there is a need for a performance standard that prescribes for these devices acceptable ranges of titer, sensitivity, and specificity and thereby minimizes the possibility that the devices may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel is aware of appreciable variation in the manufacture of *Francisella tularensis* serological reagents (excluding immunofluorescent reagents) regarding their sensitivity, specificity, and titer (Ref. 1). Sporadic cases of tularemia usually present difficult diagnostic problems because recovery of the organism in culture is often difficult. Diagnosis often depends on the outcome of serological tests. The Panel believes that general controls would not provide sufficient control over the devices' titer, sensitivity, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the devices and that there is sufficient information to establish a standard. The Panel is also aware of the availability of reference materials, performance specifications, and evaluation methods for these reagents (Ref. 2). The Panel recommends that *Francisella tularensis* immunofluorescent reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel members noted variation in the manufacture

of these reagents regarding their sensitivity, specificity, and titer. The Panel believes, however, that any variation in the sensitivity, specificity, and titer of these reagents resulting from manufacturing procedures can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and upon a review of the literature (Refs. 1 and 2).

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of tularemia. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of *Francisella tularensis* may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

Proposed Classification

FDA agrees with the Panel recommendation with respect to *Francisella tularensis* serological reagents (excluding immunofluorescent reagents) and is proposing that these devices be classified into class II (performance standards). However, FDA disagrees with the Panel recommendation with respect to *Francisella tularensis* immunofluorescent reagents and is proposing that these devices be classified into class II (performance standards). The agency has reviewed the Panel recommendation to classify this device into class I (general controls) and has sought additional data and documentation on the safety and effectiveness of these devices. The agency has reviewed the available literature pertaining to immunofluorescent reagents. The agency recognizes that the performance characteristics of immunofluorescent reagents depends appreciably upon how they are manufactured. The agency notes that immunofluorescent reagents are produced using essentially the same manufacturing procedures as those for the other serological reagents described herein. Therefore, the agency is proposing that *Francisella tularensis* immunofluorescent reagents be classified into class II (performance standards). The agency believes that performance standards are necessary for *Francisella tularensis* serological reagents because general controls alone are insufficient to control the risks to health presented by these devices. A performance standard would provide reasonable assurance of the safety and effectiveness of the devices. The agency also believes that there is sufficient information to establish a performance standard for these devices (Ref. 2).

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Jarnetz, E., J. L. Melnick, and E. A. Adelberg, "Review of Medical Microbiology," 12th Ed., Lange Medical publications, Los Altos, pp. 217–220, 1976.

2. "Specifications and Evaluation Methods for Immunological and Microbiological Reagents," Vol. 1, 4th Ed., Center for Disease Control, Public Health Service, Department of Health, Education, and Welfare, B1–8–11, 1975.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3280, to read as follows:

§ 866.3280 Francisella tularensis serological reagents.

(a) *Identification. Francisella tularensis* serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Francisella tularensis* antibodies in a patients serum and/or to identify *Francisella tularensis* in cultured isolates derived from clinical specimens. Additionally, some of these reagents consist of antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify *Francisella tularensis* directly from clinical specimens and/or cultured isolates derived from clinical specimens. The identification aids in the diagnosis of tularemia cause by *Francisella tularensis* and provides epidemiological information on this disease. Tularemia is a disease principally of rodents, but may be transmitted to humans through handling of infected animals, animal products, or by the bites of fleas and ticks. The disease takes on several forms depending upon the site of infection, such as skin lesions, lymph node enlargements, or pulmonary infection.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 6, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11787 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2169]

Medical Devices; Classification of Haemophilus spp. Serological Reagents

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Haemophilus* spp. serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation.

The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of *Haemophilus* spp. serological reagents:

1. Identification: *Haemophilus* spp. serological reagents are devices that consist of antigens and antisera Including antisera conjugated with a fluorescent dye, that are used in serological tests to identify *Haemophilus* from cultured isolates derived from clinical specimens and/or directly from clinical specimens. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus *Haemophilus* and provides epidemiological information on diseases caused by these microorganisms. Diseases most often caused by *Haemophilus* spp. include pneumonia, pharyngitis, sinusitis, vaginitis, chancroid venereal disease, and a contagious form of conjunctivitis (inflammation of eyelid membranes).

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that *Haemophilus* spp. serological reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel has noted variation in the manufacture of these reagents regarding their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedure can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and on a history of satisfactory performance of the devices.

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of diseases caused by *Haemophilus* spp. Inappropriate thereapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of *Haemophilus* spp. may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that *Haemophilus* spp. serological reagents be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3300, to read as follows:

§ 866.3300 Haemophilus spp. serological reagents.

(a) *Identification: Haemophilus* spp. serological reagents are devices that consist of antigens and antisera, including antisera conjugated with a fluorescent dye, that are used in serological tests to identify *Haemophilus* spp. from cultured isolates derived from clinical specimens and/or directly from clinical specimens. The identification aids in the diagnosis of diseases caused by bacteria belonging to the genus *Haemophilus* and provides epidemiological information on diseases caused by these microorganisms. Diseases most often caused by *Haemophilus* spp. include pneumonia, pharyngitis, sinusitis, vaginitis, chancroid venereal disease, and a contagious form of conjunctivitis (inflammation of eyelid membranes).

(b) *Classifaction.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments, are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 6, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11788 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2170]

Medical Devices; Classification of Herpes Simplex Virus Serological Reagents

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying herpes simplex virus serological reagents into class II (performance standards). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that these devices be classified into class II with the exception of herpes simplex virus complement fixation test reagents which the Panel recommended be classified into class I (general controls). The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. The effect of classifying a device into class II is to provide for future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of herpes simplex virus serological reagents:

1. Identification: Herpes simplex virus serological reagents are devices that consist of antigens and antisera used in various serological tests to identify herpes simplex virus antibodies in a patient's serum. Additionally, some of these reagents consist of herpes simplex virus antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify herpers simplex virus directly from clincial specimens and/or tissue culture isolates derived from clinical specimens. The identification aids in the diagnosis of diseases caused by herpes simplex viruses and provides epidemiological information on these diseases. Herpes simplex viral infections range from common and mild lesions of the skin and mucous membranes to a severe form of encephalitis (inflammation of the brain).

2. Recommended classification: The Microbiology Device Classification Panel recommends that herpes simplex virus serological reagents (excluding complement fixation test reagents) be classified into class II (performance standards) and that establishing a performance standard for this device be a medium priority. The Panel also recommends that herpes simplex virus complement fixation test reagents be classified into class I (general controls) and that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that herpes simplex virus serological reagents (excluding complement fixation test reagents) be classified into class II because there is a need for a performance standard that prescribes for these devices acceptable ranges of titer, sensitivity, and specificity and thereby minimizes the possibility that the devices may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Since the success of treatment of herpes simplex virus infection is determined by early diagnosis, a rapid means of diagnosis is strongly desired. Immunofluorescent procedures can produce rapid definitive determination of the virus in clinical materials. Virus neutralization tests and complement fixation are the most commonly used tests for detection of herpes simplex virus antibodies in a patient's serum. Gittzus and Rubin (Ref. 1) compared five commercial conjugates for herpes simplex virus and noted excessive nonspecific background fluorescent staining with one of the reagents. Cherry, et al. (Ref. 2) reported nonspecific staining from 12 sources of commercial conjugates due to impurity of the fluorescent dye preparations. Johnson, Beutner, and Holborow (Ref. 3) and Cherry and Reimer (Ref. 4) all warn of the variable performance of commercial conjugates and strongly advocate the need for standardization of these reagents. The Panel believes that general controls would not provide sufficient control over the devices' titer, sensitivity, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the devices and that there is sufficient information to establish a standard (Ref. 5). The Panel is also aware of the availability of reference materials, performance specifications, and evaluation methods for these reagents (Ref. 6). The Panel further recommends that herpes simplex virus complement fixation test reagents be classified into class I because the Panel believes general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel members noted variation in the manufacture of these reagents regarding their sensitivity, specificity, and titer. The Panel believes, however, that any variation in sensitivity, specificity, and titer of these reagents resulting from manufacturing procedures can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and upon a review of the literature (Refs. 1 through 4).

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of diseases caused by herpes simplex virus. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presense of herpes simplex virus may contribute to epidemiological misinformation. Consequently, the risk, of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

Proposed Classification

FDA agrees with the Panel recommendation with respect to herpes simplex virus serological reagents (excluding complement fixation test reagents) and is proposing that these devices be classified into class II (performance standards). However, FDA disagrees with the Panel recommendation with respect to herpes simplex virus complement fixation test reagents and is proposing that the devices be classified into class II (performance standards). The agency has reviewed the Panel recommendation to classify this device into class I and has sought additional data and documentation on the safety and effectiveness of this device. The agency has reviewed the available medical literature pertaining to herpes simplex virus complement fixation test reagents (Ref. 5). The agency notes that antigens for the complement fixation test and the antigens for the virus neutralization test are similar and are generally prepared from the same sources (Ref. 5). Consequently, the performance of complement fixation test reagents not only shares problems of variability common to the manufacturers of those other serological reagents described, but also exhibits a variability intrinsic to complement fixation reagents. Therefore, the agency is proposing that herpes simplex virus complement fixation reagents be classified into class II (performance standards).

The agency believes that performance standards are necessary for herpes simplex virus serological reagents cause general controls along are insufficient to control the risks to health presented by the devices. A performance standard would provide reasonable assurance of the safety and effectiveness of the devices. The agency also believes that there is sufficent information to establish a performance standard for these devices (Ref. 2).

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Gittzus, J. G. and S. J. Rubin, "Clinical Evaluation of Commercial Conjugates for Direct Immunofluorescence of Herpes Simplex Virus," *Journal of Clinical Microbiology*, 6(6): 574–577, 1977.

2. Cherry, W. B., R. M. McKinney, V. M. Emmel, J. T. Spillane, G. A. Hebert, and B. Pittman, "Evaluation of Commercial Fluorescein Isothiocvanates Used in Fluorescent Antibody Studies," *Stain Technology*, 44(4): 179–186, 1969.

3. Johnson, G. D., E. H. Beutner, and J. Holborow, "Development in Immunofluorescence: The Need for Standardization," *Journal of Clinical Pathology*, 20:720–723, 1967.

4. Cherry, W. B. and C. B. Reimer, "Standardization of Diagnostic Materials. 4. Diagnostic Immunofluorescence," *World Health Organization Bulletin*, 48(6): 737–745, 1973.

5. Tokumara, T., "Herpesvirus," *in* "Diagnostic Procedures for Viral and Rickettsial Infections," 4th Ed., Edited by Lenette, E. H., and N. S. Schmidt, American Public Health Association, Inc., New York, pp. 641–676, 1969.

6. Specifications and Evaluation Methods for Immunological and Microbiological Reagents," Vol. 2, 2d Ed., Center for Disease Control, Public Health Service, Department of Health, Education, and Welfare, B–25, 1974.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3305, to read as follows:

§ 866.3305 Herpes simplex virus serological reagents.

(a) *Identification.* Herpes simplex virus serological reagents are devices that consist of antigens and antisera used in various serological tests to identify herpes simplex virus antibodies in a patient's serum. Additionally, some of these reagents consist of herpes simplex virus antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify herpes simplex virus directly from clinical specimens and/or tissue culture isolates derived from clinical specimens. The identification aids in the diagnosis of diseases caused by herpes simplex viruses and provides epidemiological information on these diseases. Herpes simplex viral infections range from common and mild lesions of the skin and mucous membranes to a severe

form of encephalitis (inflammation of the brain).

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 6, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11789 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2173]

Medical Devices; Classification of Histoplasma Capsulatum Serological Reagents

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Histoplasma capsulatum* serological Reagents into class II (performance standards). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee made the following recommendation regarding the classification of *Histoplasma capsulatum* serological reagents:

1. Identification: *Histoplasma capsulatum* serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Histoplasma capsulatum* antibodies in a patient's serum. Additionally, some of these reagents consist of *Histoplasma capsulatum* antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify *Histoplasma capsulatum* from clinical specimens and/or cultures isolates derived from clinical specimens. The identification aids in the diagnosis of histoplasmosis caused by this fungus belonging to the genus *Histoplasma* and provides epidemiological information on diseases caused by this fungus. Histoplasmosis usually is a mild and often a symptomatic respiratory infection, but in a small number of infected individuals the lesions may spread to practically all tissues and organs.

2. Recommended classification: Class II. (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that *Histoplasma capsulatum* serological reagents be classified into class II because there is a need for a performance standard that prescribes for these devices acceptable ranges of titer, sensitivity, and specificity and thereby minimizes the possibility that the devices may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Cherry and Reimer (Ref. 1) included fluorescent antibody reagents for *Histoplasma capsulatum* among several major immunofluorescent reagents requiring standardization. The need for standardization is seen in a study by Kaufman (Ref. 2), who described two *Histoplasma capsulatum* antigen serological reagents suitable for use in the complement fixation test (an alternative serological test). This investigator warns that interpretation of the test results using this device may be difficult because of the commonly observed cross-reactivity and nonspecificity of these two reagents. DiSalvo and Corbet (Ref. 3) reported false-positive histoplasmin latex agglutination reactions in specimens from patients who apparently did not have histoplasmosis, but had proven tuberculosis. These investigators suggested that the false-positive reactions observed were due, in part, to the limited specificity of the antigen reagents. Serological evidence is often the prime factor responsible for a definitive diagnosis of histoplasmosis because diagnosis cannot always be proven by cultural isolation or histologic examination. Moreover, the fluorescent antibody technique is frequently used for rapid screening of clinical materials to identify *Histoplasma capsulatum.* The Panel believes that general controls would not provide sufficient control over the device's accuracy, titer, sensitivity, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard. The clinical experience of the Panel and its familiarity with the literature have disclosed appreciable variation in the manufacture of these reagents as to their sensitivity, specificity and titer (Refs. 1, 2, and 3). The Panel is aware of the availability of reference materials, performance specifications and evaluation methods for these reagents (Ref. 4).

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1 through 4).

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of histoplasmosis. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to identify *Histoplasma capsulatum* may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that *Histoplasma capsulatum* serological reagents be classified into class II (performance standards). The agency believes that a performance standard is necessary for these devices because general controls alone are insufficient to control the risks to health presented by the devices. A performance standard would provide reasonable assurance of the safety and effectiveness of the devices. The agency also believes that there is sufficient information to establish a performance standard for these devices.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Cherry, W. B. and C. B. Reimer, "Standardization of Diagnostic Materials, 4.

Diagnostic Immunofluorescence," *World Health Organization Bulletin,* 48:737–745, 1973.

2. Kaufman, L., "Serodiagnosis of Fungal Diseases," *in* "Manual of Clinical Microbiology," 2d Ed., edited by Lenette, E. H., E. H. Spaulding, and J. P. Truant, American Society for Microbiology, Washington, DC, pp. 561–563, 1974.

3. DiSalvo, A. F. and D. S. Corbett, "Apparent False-Positive Histoplasmin Latex Agglutination Tests in Patients with Tuberculosis," *Journal of Clinical Microbiology,* 3(3):306–308, 1976.

4. "Specifications and Evaluation Methods for Immunological and Microbiological Reagents," Vol. 1, 4th Ed., Center for Disease Control, Public Health Service, Department of Health, Education, and Welfare, C–15–18, 1975.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3320, to read as follows:

§ 866.3320 Histoplasma capsulatum serological reagents.

(a) *Identification. Histoplasma capsulatum* serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Histoplasma capsulatum* antibodies in a patient's serum. Additionally, some of these reagents consist of *Histoplasma capsulatum* antisera conjugated with a fluorescent dye (Immunofluorescent reagents) used to identify *Histoplasma capsulatum* from clinical specimens and/or cultured isolates derived from clinical specimens. The identification aids in the diagnosis of histoplasmosis caused by this fungus belonging to the genus *Histoplasma* and provides epidemiological information on the diseases caused by this fungus. Histoplasmosis usually is a mild and often asymptomatic respiratory infection, but in a small number of infected individuals the lesions may spread to practically all tissues and organs.

(b) *Classification.* Class II (performance standards).

Interested persons may on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 6, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affiars.

[FR Doc. 80–11790 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2174]

Medical Devices; Classification of Influenza Virus Serological Reagents

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying influenza virus serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of influenza virus serological reagents:

1. Identification: Influenza virus serological reagents are devices that consist of antigens and antisera and used in serological tests to identify influenza virus antibodies in a patient's serum. The identification aids in the diagnosis of influenza (flu) and provides epidemiological information on influenza. Influenza is an acute respiratory tract disease, which is often epidemic.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that influenza virus serological reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel recognizes that a definitive diagnosis of influenza virus infection by serological methods is often retrospective since the patient generally recovers (or succumbs) from the illness before the serodiagnosis can be made. The Panel also notes that there is currently no specific treatment for this disease (i.e., there is a lack of available antiviral drug therapy). Consequently, the risk of an incorrect diagnosis relates primarily to the dissemination of infection to other individuals or communities. The Panel has noted variation in the manufacture of these reagents regarding their sensitivity, specificity, and titer. The Panel believes that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedure can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and on a history of satisfactory performance of the device.

5. Risks to health: Epidemiological misinformation: Failure of the device to detect the presence of influenza virus may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates primarily to the dissemination of the infection to other individuals or communities.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that influenze virus serological reagents be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3330, to read as follows:

§ 866.3330 Influenza virus serological reagents.

(a) *Identification.* Influenza virus serological reagents are devices that consist of antigens and antisera used in serological tests to identify influenza antibodies in a patient's serum. The identification aids in the diagnosis of influenza (flu) and provides epidemiological information on influenza. Influenza is an acute respiratory tract disease, which is often epidemic.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 6, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11791 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2175]

Medical Devices; Classification of Klebsiella spp. Serological Reagents

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Klebsiella* spp. serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panal, an FDA advisory committee, made the following recommendation regarding the classification of *Klebsiella* spp. serological reagents:

1. Identification: *Klebsiella* spp. serological reagents are devices that consist of antigens and antisera, including antisera conjugated with a fluorescent dye (immunofluorescent reagents), that are used in serological tests to identify *Klebsiella* spp. from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of infections caused by bacteria belonging to the genus *Klebsiella* and provides epidemiological information on diseases caused by *Klebsiella* spp. These organisms can cause serious urinary tract and pulmonary infections, particularly in hospitalized patients.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that *Klebsiella* spp. serological reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel has noted variation in the manufacture of these reagents regarding their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedure can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and on a history of satisfactory performance of the devices.

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of diseases caused by infection. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of *Klebsiella* spp. may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that *Klebsiella* spp. serological reagents be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3340 as follows:

§ 866.3340 Klebsiella spp. serological reagents.

(a) *Identification. Klebsiella* spp. serological reagents are devices that consist of antigens and antisera, including antisera conjugated with a fluorescent dye (immunofluorescent reagents), that are used in serological tests to identify *Klebsiella* spp. from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of infections caused by bacteria belonging to the genus *Klebsiella* and provides epidemiological information on diseases caused by *Klebsiella* spp. These organisms can cause serious urinary tract and pulmonary infections, particularly in hospitalized patients.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 6, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11792 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

21 CFR Part 866

[Docket No. 78N-2176]

Medical Devices; Classification of Leptospira spp. Serological Reagents

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Leptospira* spp. serological reagents into class II (performance standards). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of *Leptospira* spp. serological reagents:

1. Identification: *Leptospira* spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to *Leptospira* spp. in a patient's serum and/or identification of *Leptospira* spp. from cultured isolates dervied from clinical specimens. Additionally, some of these antisera are conjugated with a fluorescent dye (immunofluorescent reagents) and used to identify *Leptospira* spp. directly from clinical specimens. The identification aids in the diagnosis of leptospirosis caused by bacteria belonging to the genus *Leptospira* and provides epidemiological information on this disease. Leptospirosis infections range from mild fever-producing illnesses to severe liver and kidney involvement producing hemorrhage and dysfunction of these organs.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that *Leptospira* spp. serological reagents be classified into class II because there is a need for a performance standard that prescribes for these devices acceptable ranges of titer, sensitivity, and specificity and thereby minimizes the possibility that the devices may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The clinical experience of the Panel members has disclosed appreciable variation in the manufacture of these reagents regarding their sensitivity, specificity, and titer. The Panel is aware of the availability of reference materials, performance specifications, and evaluation methods for these devices (Ref. 1). The Panel believes that general controls would not provide sufficient control over the devices' titer, sensitivity, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and upon a review of the literature (Ref. 1).

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of leptospirosis. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of *Leptospira* spp. may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that the *Leptospira* spp. serological reagents be classified into class II (performance standards). The agency believes that a performance standard is necessary for these devices because general controls alone are insufficient to control the risks to health presented by the devices. A performance standard would provide reasonable assurance of the safety and effectiveness of the devices. The agency also believes that there is sufficient information to establish a performance standard for these devices.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons from 9 a.m. to 4 p.m., Monday through Friday.

1. "Specifications and Evaluation Methods for Immunological and Microbiological Reagents," Vol. 1, 4th Ed., Center for Disease Control, Public Health Service, Department of Health, Education, and Welfare, B1-15, 1975.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3350, to read as follows:

§ 866.3350 Leptospira spp. serological reagents.

(a) *Identification. Leptospira* spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to *Leptospira* spp. in a patient's serum and/or identification of *Leptospira* spp. from cultured isolates derived from clinical specimens. Additionally, some of these antisera are conjugated with a fluorescent dye (immunofluorescent reagents) and used to identify *Leptospira* spp. directly from clinical specimens. The identification aids in the diagnosis of leptospirosis caused by bacteria belonging to the genus *Leptospira* and provides epidemiological information on this disease. Leptospirosis infections range from mild fever-producing illnesses to severe liver and kidney involvement producing hemorrhage and dysfunction of these organs.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 7, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-11793 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 866

[Docket No. 78N-2177]

Medical Devices; Classification of "Listeria" spp. Serological Reagents

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Listeria* spp. serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATE: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register**

ADDRESS: Written comments to the Office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of *Listeria* spp. serological reagents:

1. Identification: *Listeria* spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Listeria* spp. from cultured isolates derived from clinical specimens. Additionally, some of these reagents consist of *Listeria* spp. antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify *Listeria* spp. directly from clinical specimens. The identification aids in the diagnosis of listeriosis, a disease caused by bacteria belonging to the genus *Listeria,* and provides epidemiological information on diseases caused by these microorganisms. *Listeria monocytogenes,* the most common human pathogen of this genus, causes meningitis (inflammation of the brain membranes) and meningoencephalitis (inflammation of the brain and brain membranes) and is often fatal if untreated. A second form of human listeriosis is an intrauterine infection in pregnant women that results in a high mortality rate for the infant before or after birth.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that *Listeria* spp. serological reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel notes that serological diagnosis of listeriosis is seldom performed because test results are often difficult to interpret. The Panel has noted variation in the manufacture of these reagents as to their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedure can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices.

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of listeriosis. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of *Listeria* spp. may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

Proposed Classification

FDA agrees with the Panel recommendation and its proposing that *Listeria* ssp. serological reagents be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat, 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3355, to read as follows:

§ 866.3355 Listeria spp. serological reagents.

(a) *Identification. Listeria* ssp. serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Listeria* ssp. from cultured isolates derived from clinical specimens. Additionally, some of these reagents consist of *Listeria* ssp. antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify *Listeria* ssp. directly from clinical specimens. The identification aids in the diagnosis of listeriosis, a disease caused by bacteria belonging to the genus *Listeria,* and provides epidemiological information on diseases caused by these micoorganisms. *Listeria monocytogenes,* the most common human pathogen of this genus, causes meningitis (inflammation of the brain membranes) and meningoencephalitis (inflammation of the brain and brain membranes) and is often fatal if untreated. A second form of human listeriosis is an intrauterine infection in pregnant women that results in a high mortality rate for infants before or after birth.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments, are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 7, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc 80-11794 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 866

[Docket No. 78N-2178]

Medical Devices; Classification of Lymphocytic Choriomeningitis Virus Serological Reagents

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying lymphocytic choriomeningitis virus serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of lymphocytic choriomeningitis virus serological reagents:

1. Identification: Lymphocytic choriomeningitis virus serological reagents are devices that consist of antigens and antisera used in serological tests to identify lymphocytic choriomeningitis virus antibodies in a patient's serum. The identification aids in the diagnosis of lymphocytic choripmeningitis virus infection and provides epidemiological information on diseases caused by this virus. Lymphocytic choriomeningitis virus usually causes a mild cerebral meningitis (inflammation of membranes that envelop the brain) and occasionally a mild pneumonia, but in rare instances may produce severe and even fatal illnesses due to complications from cerebral meningitis and pneumonia.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that lymphocytic choriomeningitis virus serological reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel recognizes that a definitive diagnosis of lymphocytic choriomeningitis virus infection by serological methods is often retrospective since the patient generally recovers (or succumbs) from the illness before the serodiagnosis can be made. The Panel also notes that there is currently no specific treatment for the disease (i.e., there is a lack of available antiviral drug therapy). Consequently, the risk of an incorrect diagnosis relates primarily to the dissemination of infection of other individuals or communities. The Panel has noted variation in the manufacture of these reagents regarding their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedure can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and on a history of satisfactory performance of the device.

5. Risks to health: Epidemiological misinformation: Failure of the device to detect the presence of lymphocytic choriomeningitis virus may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that lymphocytic choriomeningitis virus serological reagents be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide a reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 is Subpart D by adding new § 866.3360, to read as follows:

§ 866.3360 Lymphocytic choriomeningitis virus serological reagents.

(a) *Identification.* Lymphocytic choriomeningitis virus serological reagents are devices that consist of antigens and antisera used in serological tests to identify limphocytic choriomeningitis virus antibodies in a patient's serum. The identification aids in the diagnosis of lymphocytic choriomeningitis virus infection and provides epidemiological information on diseases caused by this virus. Lymphocytic choriomeningitis virus usually causes a mild cerebral meningitis (inflammation of membranes that envelop the brain) and occasionally a mild pneumonia, but in rare instances may produce severe and even fatal illnesses due to complications from cerebral meningitis and pneumonia.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments, are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 7, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11795 Filed 4–21–80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 866

[Docket No. 78N–2179]

Medical Devices; Classification of Mycobacterium Tuberculosis Immunofluorescent Reagents

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Mycobacterium tuberculosis* immunofluorescent reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30

days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of *Mycobacterium tuberculosis* immunofluorescent reagents:

1. Identification: *Mycobacterium tuberculosis* immunofluorescent reagents are devices that consist of antisera conjugated with a fluorescent dye used to identify *Mycobacterium tuberculosis* directly from clinical specimens. The identification aids in the diagnosis of tuberculosis and provides epidemiological information on this disease. *Mycobacterium tuberculosis* is the common causative organism in human tuberculosis, a chronic infectious disease characterized by formation of tubercles (small rounded nodules) and tissue necrosis (destruction), usually occurring in the lung.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that *Mycobacterium tuberculosis* immunofluorescent reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel members have noted variation in the manufacture of these reagents regarding their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedure can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of these devices.

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of tuberculosis. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of *Mycobacterium tuberculosis* may contribute to epidemiological misinformation. Consequently, an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that *Mycobacterium tuberculosis* immunofluorescent reagents be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3370, to read as follows:

§ 866.3370 Mycobacterium tuberculosis immunofluorescent reagents.

(a) *Identification: Mycobacterium tuberculosis* immunofluorescent reagents are devices that consist of antisera conjugated with a fluorescent dye used to identify *Mycobacterium tuberculosis* directly from clinical specimens. The identification aids in the diagnosis of tuberculosis and provides epidemiological information on this disease. *Mycobacterium tuberculosis* is the common causative organism in human tuberculosis, a chronic infectious disease characterized by formation of tubercles (small rounded nodules) and tissue necrosis (destruction), usually occurring in the lung.

(b) *Classification:* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857 written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 7, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11796 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2180]

Medical Devices; Classification of Mycoplasma spp. Serological Reagents

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Mycoplasma* spp. serologial reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATE: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of *Mycoplasma* spp. serological reagents:

1. Identification: *Mycoplasma* spp. serological reagents are devices that consist of antigens and antisera used is serological tests to identify *Mycoplasma* spp. antibodies

in a patient's serum. Additionally, some of these reagents consist of *Mycoplasma* spp. antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify *Mycoplasma* spp. directly from clinical specimens. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus *Mycoplasma* and provides epidemiological information on diseases caused by these microorganisms. *Mycoplasma* spp. are associated with inflammatory conditions of the urinary and respiratory tracts, the genitals, and the mouth. The effects in humans of infection with *Mycoplasma pneumoniae* range from inapparent infection to mile or severe upper respiratory disease, ear infection, and bronchial pneumonia.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that *Mycoplasma* spp. serological reagents be classified into class I because the panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel has noted variation in the manufacture of these reagents regarding their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedure can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and on a history of satisfactory performance of the devices.

5. Risks to health: Epidemiological misinformation: Failure of the device to detect the presence of *Mycoplasma* spp. may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates primarily to the dissemination of infection to other individuals or communities.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that *Mycoplasma* spp. serological reagents be classified into class I (general controls) with no exemptions. The agency believes that these controls are sufficient to provide reasonable assurance of the safety and effectiveness of the devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3375, to read as follows:

§ 866.3375 Mycoplasma spp. serological reagents.

(a) Identification: *Mycoplasma* spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Mycoplasma* spp. antibodies in a patient's serum. Additionally, some of these reagents consist of *Mycoplasma* spp. antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify *Mycoplasma* spp. directly from clinical specimens. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus *Mycoplasma* and provides epidemiological information on diseases caused by these microorganisms. *Mycoplasma* spp. are associated with inflammatory conditions of the urinary and respiratory tracts, the genitals, and the mouth. The effects in humans of infection with *Mycoplasma pneumoniae* range from inapparent infection to mild or severe upper respiratory disease, ear infection, and bronchial pneumonia.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11797 Filed 4–21–80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 866

[Docket No. 78N–2181]

Medical Devices; Classification of Mumps Virus Serological Reagents

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying mumps virus serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of mumps virus serological reagents:

1. Identification: Mumps virus serological reagents consist of antigens and antisera used in serological tests to identify mumps virus antibodies in a patient's serum. Additionally, some of these reagents consist of antisera conjugated with a fluorescent dye (immunofluorescent reagents) used in serological tests to identify mumps viruses from tissue culture isolates derived from clinical specimens. The identification aids in the diagnosis of mumps and provides epidemiological information on mumps. Mumps is an acute contagious disease, particularly in children, characterized by an enlargement of one or both of the parotid glands (glands situated near the ear), although other organs may also be involved.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that mumps virus serological reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel recognizes that a definitive diagnosis of mumps virus infection by serological methods is often retrospective since the patient generally recovers (or succumbs) from the illness before the serodiagnosis can be made. The Panel also notes there is currently no

specific treatment for the disease (i.e., there is a lack of available antiviral drug therapy). Consequently, the risk of an incorrect diagnosis relates primarily to the dissemination of infection to other individuals or communities. The Panel members noted variation in the manufacture of these reagents regarding their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedures can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and on a history of satisfactory performance of the devices.

5. Risks to health: Epidemiological misinformation: Failure of the device to detect the presence of mumps viruses may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates primarily to the dissemination of infection to other individuals or communities.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that mumps virus serological reagents be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3380, to read as follows:

§ 866.3380 Mumps virus serological reagents.

(a) *Identification.* Mumps virus serological reagents consist of antigens and antisera used in serological tests to identify mumps virus antibodies in a patient's serum. Additionally, some of these reagents consist of antisera conjugated with a fluorescent dye (immunofluorescent reagents) used in serological tests to identify mumps viruses from tissue culture isolates derived from clinical specimens. The identification aids in the diagnosis of mumps and provides epidemiological information on mumps. Mumps is an acute contagious disease, particularly in children, characterized by an enlargement of one or both of the parotid glands (glands situated near the ear), although other organs may also be involved.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 7, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11798 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2182]

Medical Devices; Classification of Neisseria spp. Direct Serological Test Reagents

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Neisseria* spp. direct serological test reagents into class II (performance standards). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of *Neisseria* spp. direct serological test reagents:

1. Identification: *Neisseria* spp. direct serological test reagents are devices that consist of antigens and antisera used in serological tests to identify *Neisseria* spp. from cultured isolates derived from clinical specimens. Additionally, some of these reagents consist of *Neisseria* spp. antisera conjugated with a fluorescent dye (immunofluorescent reagents) which may be used to detect the presence of *Neisseria* spp. directly from clinical specimens. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus *Neisseria*, such as epidemic cerebrospinal meningitis, meningococcal disease, and gonorrhea, a venereal disease, and also provides epidemiological information on diseases caused by these microorganisms. The device does not include products for the detection of gonorrhea in humans by indirect methods, such as detection of antibodies or of oxidase produced by gonococcal organisms.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for these devices be a high priority.

3. Summary of reasons for the recommendation: The Panel recommends that *Neisseria* spp. direct serological test reagents be classified into class II because there is a need for a performance standard that prescribes for these devices acceptable ranges of titer, sensitivity, and specificity and thereby minimizes the possibility that the devices may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. There is a need for standardization since cross-reactions (lack of specificity) among *Neisseria* spp. and other unrelated bacteria are frequently encountered with immunofluorescent reagents as well as with other serological reagents (Refs. 1 and 2). Cherry and Reimer (Ref. 3) included fluorescent antibody reagents for *Neisseria gonorrhoeae* and *Neisseria meningitidis* among major immunofluorescent reagents requiring the highest priority for standardization. The Panel believes that general controls would not provide sufficient control over the devices' titer, sensitivity, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the devices and that there is sufficient information to establish a standard. The clinical experience

of the Panel members and their familiarity with the literature has disclosed appreciable variation in the manufacture of these reagents as to their sensitivity, specificity, and titer (Refs. 1, 2, and 3). The Panel is aware of the availability of reference materials, performance specifications, and evaluation methods for these reagents (Ref. 4). *Neisseria meningitidis* is the prominent cause of epidemic cerebrospinal meningitis, an inflammation of the brain and spinal cord membranes. Meningococcemia is a form of membrane disease not involving the membranes which envelope the brain or spinal cord, that may result from invasion of the blood stream by *Neisseria meningitidis.* The resulting blood infection may cause massive hemorrhage near the kidneys accompanied by widespread blood coagulation within the blood vessels. If the above conditions are undetected and untreated, the outcome is usually fatal. Gonorrhea is a highly contagious venereal disease usually transmitted by sexual intercourse, but which may also be acquired by a newborn from the mother. *Neisseria gonorrhoeae* is characterized in men by acute pus producing inflammation of the urethra and in women by inflammation of the cervix. Infection may also spread to the joints resulting in a condition called gonococcal arthritis. Immunofluorescent microscopy is frequently used to detect *Neisseria* spp. in various body fluids such as cerebrospinal fluid and the synovial fluid in joint cavities.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and upon a review of the literature (Refs. 1 through 4).

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of diseases caused by *Neisseria* spp. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of *Neisseria* spp. may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that *Neisseria* spp. direct serological test reagents be classified into class II (performance standards). The agency believes that a performance standard is necessary for these devices because general controls alone are insufficient to control the risks to health presented by these devices. A performance standard would provide reasonable assurance of the safety and effectiveness of the devices. The agency believes that there is sufficient information to establish a performance standard for these devices.

The proposed regulation would not apply to products for the detection of gonorrhea in humans by indirect methods, such as by detection of antibody or of oxidase produce by gonorrhea organisms. Such products were declared to be new drugs in a notice published in the **Federal Register** of January 29, 1974 (39 FR 3705). The products are now class III devices subject to premarket approval because the Medical Device Amendments of 1976 broadened the definition of device (21 U.S.C. 321(h)) and classified into class III those devices that FDA had previously declared to be new drugs (21 U.S.C. 360j(1)).

References

1. Collin, B. W., *"Neisseria meningitidis* (Meningococcus)," *in* "Manual of Clinical Microbiology," 2d Ed., Edited by Lennette, E. H., E. H. Spaulding, and J. P. Truant, American Society for Microbiology, Washington, DC, pp. 116–123, 1974.

2. Kellog, D. S., Jr. *"Neisseria gonorrhoeae* (Gonococcus)," *in* "Manual of Clinical Microbiology," 2d Ed., Edited by Lennette, E. H., E. H. Spaulding, and J. P. Truant, American Society for Microbiology, Washington, DC, pp. 124–129, 1974.

3. Cherry, W. B. and C. B. Reimer, "Standardization of Diagnostic Material, 4. Diagnostic Immunofluorescence," *World Health Organization Bulletin,* 48:737–745, 1973.

4. "Specifications and Evaluation Methods for Immunological and Microbiological Reagents," Volume 1, 4th Ed., Center for Disease Control, Public Health Service, Department of Health, Education, and Welfare, B–111–12, 1975.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3390, to read as follows:

§ 866.3390 Neisseria spp. direct serological test reagents

(a) *Identification. Neisseria* spp. direct serological test reagents are devices that consist of antigens and antisera used in serological tests to identify *Neisseria* spp. from cultured isolates. Additionally, some of these reagents consist of *Neisseria* spp. antisera conjugated with a fluorescent dye (immunofluorescent reagents) which may be used to detect the presence of *Neisseria* spp. directly from clinical specimens. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus *Neisseria,* such as epidemic cerebrospinal memingitis, meningococcal disease, and gonorrhea, a venereal disease, and also provides epidemiological information on diseases caused by these microorganisms. The device does not include products for the detection of gonorrhea in humans by indirect methods, such as detection of antibodies or of oxidase produced by gonococcal organisms.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affiars.

[FR Doc. 80–11799 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2183]

Medical Devices; Classification of Parainfluenza Virus Serological Reagents

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying parainfluenza virus serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:
Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of parainfluenza virus serological reagents:

1. Identification: Parainfluenza virus serological reagents are devices that consist of antigens and antisera used in serological tests to identify parainfluenza virus antibodies in a patient's serum. The identification aids in the diagnosis of parainfluenza virus infections and provides epidemiological information on diseases caused by these viruses. Parainfluenza viruses cause many respriatory illnesses ranging from the common cold to pneumonia.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that parainfluenza virus serological reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel recognizes that a definitive diagnosis of parainfluenza virus infection by serological methods is often retrospective since the patient generally recovers (or succumbs) from the illness before the serodiagnosis can be made. The Panel also notes that there is currently no specific treatment for the diseases cause by this virus (i.e., there is a lack of available antiviral drug therapy). Consequently, the risk of an incorrect diagnosis relates primarily to the dissemination of infection to other individuals or communities. The Panel has noted variation in the manufacture of these reagents as to their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedure can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and on a history of satisfactory performance of the devices.

5. Risks to health: Epidemiological misinformation: Failure of the device to detect the presence of parainfluenza viruses may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates primarily to the dissemination of infection to other individuals or communities.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that parainfluenza virus serological reagents be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3400, to read as follows:

§ 866.3400 Parainfluenza virus serological reagents.

(a) *Identification.* Parainfluenza virus serological reagents are devices that consist of antigens and antisera used in serological tests to identify parainfluenza virus antibodies in a patient's serum. The identification aids in the diagnosis of parainfluenza virus infections and provides epidemiological information on diseases caused by these viruses. Parainfluenza viruses cause many respiratory illnesses ranging from the common cold to pneumonia.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 7, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11800 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2184]

Medical Devices; Classification of Poliovirus Serological Reagents

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying poliovirus serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:
Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of poliovirus serological reagents:

1. Identification: Poliovirus serological reagents are devices that consist of antigens and antisera used in serological tests to identify poliovirus antibodies in a patient's serum. Additionally, some of these reagents consist of poliovirus antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify polioviruses from clinical specimens and/or from tissue culture isolates derived from clinical specimens. The identification aids in the diagnosis of poliomyelitis and provides epidemiological information on this disease. Poliomyelitis (polio) is an acute infectious disease, which in its serious form affects the central nervous system. Polio virus can destroy portions of the spinal cord motor neuronn, causing debilitating paralysis.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that poliovirus serological reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel recognizes that a definitive diagnosis of poliovirus infection by serological methods is often retrospective since the patient generally recovers (or succumbs) from the illness before the serodiagnosis can be made. The Panel also notes that there is no specific treatment at this time for the disease (i.e., there is a lack of available antiviral drug therapy). Consequently, the risk of an incorrect diagnosis relates primarily to the dissemination of infection to other individuals or communities. The Panel members noted variation in the manufacture of these reagents with respect to their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedure can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and on a history of satisfactory performance of the devices.

5. Risks to health: Epidemiological misinformation: failure of the device to detect the presence of polioviruses, may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that poliovirus serological reagents be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3405, to read as follows:

§ 866.3405 Poliovirus serological reagents.

(a) *Identification.* Poliovirus serological reagents are devices that consist of antigens and antisera used in serological tests to identify poliovirus antibodies in a patient's serum. Additionally, some of these reagents consist of poliovirus antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify polioviruses from clinical specimens and/or from tissue culture isolates derived from clinical specimens. The identification aids in the diagnosis of poliomyelitis and provides epidemiological information in this disease. Poliomyelitis (polio) is an acute infectious disease, which in its serious form affects the central nervous system.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 7, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11801 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2185]

Medical Devices; Classification of Proteus spp. (Weil-Felix) Serological Reagents

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Proteus* spp. (Weil-Felix) serological reagents into class I (general controls). The FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of *Proteus* spp. (Weil-Felix) serological reagents:

1. Identification: *Proteus* spp. (Weil-Felix) serological reagents are devices that consist of antigens and antisera, including antisera conjugated with a fluorescent dye (immunofluorescent reagents), derived from the bacterium *Proteus vulgaris* used in agglutination tests (a specific type of antigen-antibody reaction) for the detection of antibodies to reckettsia (virus-like bacteria) in a patient's serum. Test results aid in the diagnosis of diseases caused by rickettsia, such a typhus fever and rocky mountain spotted fever, and provides epidemiological information on these diseases. The Panel reviewed this generic type of device identified by the name "*Proteus* spp. serological reagents."

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that *Proteus* spp. (Weil-Felix) serological reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel has noted variation in the manufacture of these reagents as to their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity and titer resulting from manufacturing procedure can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and on a history of satisfactory performance of the devices.

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of diseases; such as typhus fever and rocky mountain spotted fever. Inappropriate therapy based on inaccurate diagnositc data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of rocky

mountain spotted fever and typhus fever may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that *Proteus* ssp. (Weil-Felix) serological reagents be classified into class I (general controls) and with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3410, to read as follows:

§ 866.3410 Proteus spp. (Weil-Felix) serological reagents.

(a) *Identification. Proteus* spp. (Weil—Felix) serological reagents are devices that consist of antigens and antisera, including antisera conjugated with a fluorescent dye (immunofluorescent reagents), derived from the bacterium *Proteus vulgaris* used in agglutination tests (a specific type of antigen-antibody reaction) for the detection of antibodies to rickettsia (virus-like bacteria) in a patient's serum. Test results aid in the diagnosis of disease caused by rickettsia, such as typhus fever and rocky mountain spotted fever, and provides epidemiological information on these diseases.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m and 4 p.m., Monday through Friday.

Dated: March 7, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc 80–11802 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

21 CFR Part 866

[Docket No. 78N–2186]

Medical Devices; Classification of Pseudomonas spp. Serological Reagents

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Pseudomonas* spp. serological reagents into class II (performance standards). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register**.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of *Pseudomonas* spp. serological reagents:

1. Identification: *Pseudomonas* spp. serological reagents are devices that consist of antigens and antisera, including antisera conjugated with a fluorescent dye (immunofluorescent reagents), used to identify *Pseudomonas* spp. from clinical specimens and/or from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus *Pseudomonas*. *Pseudomonas aeruginosa* is a major cause of hospital-acquired infections, and has been associated with urinary tract infections, eye infections, burn and wound infections, blood poisoning, abscesses, and meningitis (inflamation of brain membranes). *Pseudomonas pseudomallei* causes melioidosis, a chronic pneumonia.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that *Pseudomonas* spp. serological reagents be classified into class II because there is a need for a performance standard that prescribes for these devices acceptable ranges of titer, sensitivity, and specificity and thereby minimizes the possibility that the devices may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The clinical experience of the Panel members and their familiarity with the literature has disclosed appreciable variation in the manufacture of these reagents regarding their sensitivity, specificity, and titer (Refs. 1, 2, and 3). The Panel is aware of the availability of reference materials, performance specifications, and evaluation methods for these reagents (Ref. 4). Johnson, et al. (Ref. 1), Cherry, et al., and Moody (Ref. 2) warn of the lack of precision in testing performed with commercial immunofluorescent reagents and advocate the need for their standardization. Fox, et al. (Ref. 3) advise clinicians to test carefully the sensitivity and specificity of commercially produced reagents because of their observed variability. The Panel believes that general controls would not provide sufficient control over the devices' titer, sensitivity, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the devices and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1 through 4).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of disease caused by *Pseudomonas* spp. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that *Pseudomonas* spp. serological reagents be classified into class II (performance standards). The agency believes that a performance standard is necessary for these devices because general controls alone are insufficient to control the risks to health presented by the devices. A performance standard would provide reasonable assurance of the safety and effectiveness of the devices. The agency

also believes that there is sufficient information to establish a performance standard for these devices.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Johnson, G. D., E. H. Beutner, and E. J. Holborow, "Developments in Immunofluorescence: The Need for Standardization," *Journal of Clinical Pathology*, 20:720–723, 1967.

2. Cherry, W. B. and C. B. Reimer, "Standardization of Diagnostic Materials, 4. Diagnostic Immunofluoresence," *World Health Organiztion Bulletin*, 48(6):737–745, 1973.

3. Fox, H. A., et al., "Immunofluorescence in the Diagnosis of Acute Bacterial Meningitis: A Cooperative Evaluation of the Technique in a Clinical Laboratory Setting," *Pediatrics*, 43(1):44–49, 1969.

4. "Specification and Evaluation Methods for Immunological and Microbiological Reagents," Vol. 1, 4th Ed., Center for Disease Control, Public Health Service, Department of Health, Education, and Welfare, B1–19, 1975.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3415, to read as follows:

§ 866.3415 Pseudomonas spp. serological reagents.

(a) *Identification. Pseudomonas* spp. serological reagents are devices that consist of antigens and antisera, including antisera conjugated with a fluorescent dye (immunofluorescent reagents), used to identify *Pseudomonas* spp. from clinical specimens and/or from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus *Pseudomonas*. *Pseudomonas aeruginosa* is a major cause of hospital-acquired infections, and has been associated with urinary tract infections, eye infections, burn and wound infections, blood poisoning, absecesses, and meningitis (inflammation of brain membranes). *Pseudomonas pseudomallei* causes melioidosis, a chronic pneumonia.

(b) *Classification.* Class II (performance standards.)

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments, are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 7, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11803 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2187]

Medical Devices; Classification of Rabiesvirus Immunofluorescent Reagents

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying rabiesvirus immunofluorescent reagents into class II (performance standards). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of rabiesvirus immunofluorescent reagents:

1. Identification: Rabiesvirus immunofluorescent reagents are devices that consist of rabiesvirus antisera conjugated with a fluorescent dye used to identify rabiesviruses in specimens taken from suspected rabid animals. The identification aids in the diagnosis of rabies in patients exposed by animal bite and provides epidemiological information on rabies. Rabies is an acute infectious disease of the central nervous system which, if undiagnosed, may be fatal. The disease is commonly transmitted to humans by a bite from a rabid animal.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that rabiesvirus immunofluorescent reagents be classified into class II because there is a need for a performance standard that prescribes for these devices acceptable ranges of titer, sensitivity, and specificity and thereby minimizes the possibility that the devices may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Therefore, it is extremely important to be able to demonstrate accurately whether rabiesviruses are present in an animal that has bitten someone. The fluorescent rabies antibody test makes possible a rapid diagnosis in cases of animal rabies. Cherry and Reimer (Ref. 1) included immunofluorescent reagents for rabiesviruses as high-priority reagents requiring standardization. The Panel believes that general controls would not provide sufficient control over the device's titer, sensitivity, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard. The clinical experience of the Panel members and their familiarity with the literature has disclosed appreciable variation in the manufacture of these reagents regarding their sensitivity, specificity, and titer. The Panel is aware of the availability of reference materials, performance specifications, and evaluation methods (Refs. 6 and 7) for the devices.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1–7).

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of these devices to perform satisfactorily may lead to an error in the diagnosis of rabies. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

(b) Epidemiological misinformation: Failure of the device to detect the presence of rabiesviruses may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that rabiesvirus immuofluorescent reagents be classified into class II (performance standards). The agency believes that a performance standard is necessary for these devices because general controls alone are insufficient to control the risks to health presented by the devices. A performance standard would provide reasonable assurance of the safety and effectiveness of the devices. The agency also believes that there is sufficient information to establish a performance standard for these devices.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Cherry, W. B. and C. B. Reimer, "Standardization of Diagnostic Material, 4. Diagnostic Immunofluorescence," *World Health Organization Bulletin,* 48(6):737–745, 1973.

2. "Specifications and Evaluation Methods for Immunological and Microbiological Reagents," Vol. 2, 4th Ed., Center for Disease Control, Public Health Service, Department of Health, Education, and Welfare, C1–2–6, 1974.

3. Johnson, H. N., "Rabiesvirus," *Diagnostic Procedures for Viral and Rickettsial Infections,* 4th Ed., edited by Lennette, E. H. and N. J. Schmidt, American Public Health Association, Inc., New York, pp. 312–353, 1969.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3460, to read as follows:

§ 866.3460 Rabiesvirus immunofluorescent reagents.

(a) *Identification.* Rabiesvirus immunofluorescent reagents are devices that consist of rabiesvirus antisera conjugated with a fluorescent dye used to identify rabiesviruses in specimens taken from suspected rabid animals. The identification aids in the diagnosis of rabies in patients exposed by animal bite and provides epidemiological information on rabies. Rabies is an acute infectious disease of the central nervous system which, if undiagnosed, may be fatal. The disease is commonly transmitted to humans by a bite from a rabid animal.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments, are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 7, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11804 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2188]

Medical Devices; Classification of Reovirus Serological Reagents

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying reovirus serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATE: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of reovirus serological reagents:

1. Identification: Reovirus serological reagents are devices that consist of antigens and antisera used in serological tests to identify reovirus antibodies in a patient's serum. The identification aids in the diagnosis of reovirus infections and provides epidemiological information on diseases caused by these viruses. Reoviruses are thought to cause only mild respiratory and gastrointestinal illnesses.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that reovirus serological reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel recognizes that a definitive diagnosis of reovirus infections by serological methods is often retrospective since the patient generally recovers from the illness before the serodiagnosis can be made. The Panel also notes that there is currently no specific treatment for the disease(s) (i.e., there is a lack of available antiviral drug therapy). Consequently, the risk of an incorrect diagnosis relates primarily to the dissemination of infection to other individuals or communities. The Panel members have noted variation in the manufacture of these reagents as to their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedure can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and on a history of satisfactory performance of the devices.

5. Risks to health: Epidemiological misinformation: Failure of the device to detect the presence of reoviruses may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that reovirus serological reagents be

classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3470, to read as follows:

§ 866.3470 Reovirus serological reagents.

(a) *Identification.* Reovirus serological reagents are devices that consist of antigens and antisera used in serological tests to identify reovirus antibodies in a patient's serum. The identification aids in the diagnosis of reovirus infections and provides epidemiological information on diseases caused by these viruses. Reoviruses are thought to cause only mild respiratory and gastrointestinal illnesses.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 7, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11805 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2189]

Medical Devices; Classification of Respiratory Syncytial Virus Serological Reagents

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying respiratory syncytial virus serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of respiratory syncytial virus serological reagents:

1. Identification: Respiratory syncytial virus serological reagents are devices that consist of antigens and antisera used in serological tests to identify respiratory syncytial virus antibodies in a patient's serum. Additionally, some of these reagents consist of respiratory syncytial virus antisera conjugated with a fluorescent dye (immunofluorescent reagents) and used to identify respiratory syncytial viruses from clinical specimens and/or from tissue culture isolates derived from clinical specimens. The identification aids in the diagnosis of respiratory syncytial virus infections and provides epidemiological information on diseases caused by these viruses. Respiratory syncytial viruses cause a number of respiratory tract infections, including the common cold, pharyngitis, and infantile bronchopneumonia.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that respiratory syncytial virus serological reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel recognizes that a definitive diagnosis of respiratory syncytial virus infections by serological methods is often retrospective since the patient generally recovers (or succumbs) from the illness before the serodiagnosis can be made. The Panel also notes that there is currently no specific treatment for the disease(s) (i.e., there is a lack of available antiviral drug therapy). Consequently, the risk of an incorrect diagnosis relates primarily to the dissemination of infections to other individuals or communities. The Panel has noted variation in the manufacture of these reagents as to their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedures can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and on a history of satisfactory performance of the devices.

5. Risks to health: Epidemiological misinformation: Failure of the device to detect the presence of respiratory syncytial viruses may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates primarily to the dissemination of infection to other individuals or communities.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that respiratory syncytial virus serological reagents be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3480, to read as follows:

§ 866.3480 Respiratory syncytial virus serological reagents.

(a) *Identification.* Respiratory syncytial virus serological reagents are devices that consist of antigens and antisera used in serological tests to identify respiratory syncytial virus antibodies in a patient's serum. Additionally, some of these reagents consists of respiratory syncytial virus antisera conjugated with a fluorescent dye (immunofluorescent reagents) and used to identify respiratory syncytial viruses from clinical specimens and/or from tissue culture isolates derived from clincial specimens. The identification

aids in the diagnosis of respiratory syncytial virus infections and provides epidemiological information on diseases caused by these viruses. Respiratory syncytial viruses cause a number of respiratory tract infections, including the common cold, pharyngitis, and infantile bronchopneumonia.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 7, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11806 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2190]

Medical Devices; Classification of Rhinovirus Serological Reagents

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying rhinovirus serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of rhinovirus serological reagents:

1. Identification: Rhinovirus serological reagents are devices that consist of antigens and antisera used in serological tests to identify rhinovirus antibodies in a patient's serum. The identification aids in the diagnosis of rhinovirus infections and provides epidemiological information on diseases caused by these viruses. Rhinoviruses cause common colds.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that rhinovirus serological reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel recognizes that a definitive diagnosis of rhinovirus infections by serological methods is often retrospective since the patient generally recovers from the illness before the serodiagnosis can be made. The Panel also notes that there is currently no specific treatment for the disease(s) (i.e., there is a lack of available antiviral drug therapy). Consequently, the risk of an incorrect diagnosis relates primarily to the dissemination of infection to other individuals or communities. The Panel members have noted variation in the manufacture of these reagents as to their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedure can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and on a history of satisfactory performance of the devices.

5. Risks to health: Epidemiological misinformation: Failure of the device to detect the presence of rhinoviruses may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates primarily to the dissemination of infection to other individuals or communities.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that rhinovirus serological reagents be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3490, to read as follows:

§ 866.3490 Rhinovirus serological reagents.

(a) *Identification.* Rhinovirus serological reagents are devices that consist of antigens and antisera used in serological tests to identify rhinovirus antibodies in a patient's serum. The identification aids in the diagnosis of rhinovirus infections and provides epidemiological information on diseases caused by these viruses. Rhinoviruses cause common colds.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 7, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11807 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2191]

Medical Devices; Classification of Rickettsia Serological Reagents

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying rickettsia serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of rickettsia serological reagents:

1. Identification: Rickettsia serological reagents are devices that consist of antigens and antisera used in serological tests to identify rickettsial antibodies in a patient's serum. Additionally, some of these reagents consist of rickettsial antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify rickettsia directly from clinical specimens as well as to detect rickettsial antibodies in a patient's serum. The identification aids in the diagnosis of diseases caused by bacteria belonging to the genus *Rickettsiae* and provides epidemiological information on rickettsial diseases. Rickettsia are generally transmitted by arthropods (e.g., ticks and mosquitoes) and produce infections in humans characterized by rash and fever (e.g., typhus fever, spotted fever, Q fever, and trench fever).

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that rickettsia serological reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel recognizes that serological testing for detection and quantitation of rickettsial antibodies is the method of choice for laboratory diagnosis of rickettsial diseases. The Panel also notes that because the prevalence of rickettsial diseases in the U.S. is low, these reagents are infrequently used. The Panel members have noted variation in the manufacture of these reagents as to their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedure can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of these reagents to perform satisfactorily may lead to an error in the diagnosis of diseases caused by rickettsial infection. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of rickettsia may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that rickettsia serological reagents be classified into class I (general controls) with no exemptions. The agency believes that these controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3500, to read as follows:

§ 866.3500 Rickettsia serological reagents.

(a) *Identification.* Rickettsia serological reagents are devices that consist of antigens and antisera used in serological tests to identify rickettsial antibodies in a patient's serum. Additionally, some of these reagents consist of rickettsial antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify rickettsia directly from clinical specimens as well as to detect rickettsial antibodies in a patient's serum. The identification aids in the diagnosis of diseases caused by bacteria belonging to the genus *Rickettsiae* and provides epidemiological information on rickettsial diseases. Rickettsia are generally transmitted by arthropods (e.g., ticks and mosquitoes) and produce infections in humans characterized by rash and fever (e.g., typhus fever, spotted fever, Q fever, and trench fever).

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 7, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11808 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2192]

Medical Devices; Classification of Rubella Virus Serological Reagents

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying rubella virus serological reagents into class II (performance standards). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based

on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of rubella virus serological reagents:

1. Identification: Rubella virus serological reagents are devices that consist of antigens and antisera used in serological tests to identify rubella virus antibodies in a patient's serum. The identification aids in the diagnosis of rubella (German measles) or confirmation of a person's immune status from past infections or immunizations and provides epidemiological information on German measles. Newborns who had been infected with rubella virus in the uterus may be born with multiple congenital defects (rubella syndrome).

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that rubella virus serological reagents be classified into class II because there is a need for a performance standard that prescribes for these devices acceptable ranges of titer, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient or fetus at risk unnecessarily. There is no specific treatment for rubella infection unless the patient has laboratory-proven rubella and is a pregnant woman in first 10 weeks of pregnancy, in which case abortion may be considered to avoid birth of malformed infants. Laboratory-proven rubella in the first 10 weeks of pregnancy is usually associated with fetal infection. Serological testing for detection of rubella virus antibodies is the method of choice for laboratory diagnosis of rubella infections. The Panel believes that general controls would not provide sufficient control over the devices' titer, sensitivity, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the devices and that there is sufficient information to establish a standard. The clinical experience of the Panel and its familiarity with the literature has disclosed appreciable variation in these tests regarding their sensitivity, specificity, and titer (Refs. 1 through 4). The Panel is aware of the availability of reference materials, performance specifications, and evaluation methods for some of the reagents (Refs. 5 and 6). Lennette, Schmidt, and Magoffin (Ref. 1) compared the results obtained with four conventional tests used in the diagnosis of rubella virus infections and reported discrepant results. The hemagglutination inhibition (HI) test (one of the four tests mentioned above) is one of the most commonly used in the diagnosis of rubella. The reliability of the rubella test depends on the removal of nonspecific serum hemagglutination inhibitors from a patient's serum. Schmidt and Lennette (Ref. 2) reported false-negative false-positive reactions with all three of the methods used to remove nonspecific serum hemagglutination inhibitors from serum. Haukenes and Blom (Ref. 3) observed variable quality in different batches of dextran sulfate used in the dextran sulfate/calcium chloride method of the HI test. Data (unpublished) from the premarket testing program (1971–1975) at the Center for Disease Control (CDC) demonstrate the variability of these reagents when compared with CDC's performance requirements (Ref. 4).

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel member's personal knowledge of, and clinical experience with, the devices and upon a review of the literature (Refs. 1 through 6).

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of these devices to perform satisfactorily may lead to an error in the diagnosis of diseases caused by rubella virus. Inappropriate therapy based on inaccurate diagnostic data may place the patient or fetus at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of rubella virus may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that the rubella virus serological reagents be classified into class II (performance standards). The agency believes that a performance standard is necessary for these devices because general controls alone are insufficient to control the risks to health presented by the devices. A performance standard would provide reasonable assurance of the safety and effectiveness of the devices. The agency believes that there is sufficient information to establish a performance standard for these devices.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Lennette, E. H., N. J. Schmidt, and R. L. Magoffin, "The Hemagglutination Inhibition Test for Rubella: A Comparison of Its Sensitivity to That of Neutralization, Complement Fixation, and Fluorescent Antibody Tests for Diagnosis of Infection and Determination of Immune Status," *Journal of Immunology*, 99:785–793, 1967.

2. Schmidt, N. J. and E. H. Lennette, "Variables in the Rubella Hemagglutination Inhibition Test System and Their Effect on Antigen and Antibody Titers," *Applied Microbiology*, 19:491–504, 1970.

3. Haukenes, G. and H. Blom, "False-Positive Rubella Virus Hemagglutination Inhibition Reaction: Occurrence and Disclosure," *Medical Microbiology and Immunology*, 161:99–106, 1975.

4. "Results of a Five Year (1971–1975) Premarket Evaluation Program for Commercial Microbiological Diagnostic Products," Center for Disease Control, Public Health Service, Department of Health, Education, and Welfare (unpublished).

5. "Specifications and Evaluation Methods for Immunological and Microbiological Reagents," Vol. 2, 2d Ed., Center for Disease Control, Public Health Service, Department of Health, Education, and Welfare, B–25, 1974.

6. Plotkin, S. A., "Rubella Virus," *in* "Diagnostic Procedures for Viral and Ricksettsial Infections," 4th Ed., edited by Lennette, E. H. and N. J. Schmidt, American Public Health Association, Inc., New York, pp. 364–413, 1969.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3510, to read as follows:

§ 866.3510 Rubella virus serological reagents.

(a) *Identification.* Rubella virus serological reagents are devices that consist of antigens and antisera used in serological tests to identify rubella virus antibodies in a patient's serum. The identification aids in the diagnosis of rubella (German measles) or confirmation of a person's immune status from past infections or immunizations and provides epidemiological information on German measles. Newborns infected in the uterus with rubella virus may be born with multiple congenital defects (rubella syndrome).

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before April 21, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 7, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11809 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2193]

Medical Devices; Classification of Rubeola (Measles) Virus Serological Reagents

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying rubeola (measles) virus serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of rubeola virus serological reagents:

1. Identification: Rubeola (measles) virus serological reagents are devices that consist of antigens and antisera used in serological tests to identify rubeola (measles) virus antibodies in a patient's serum. The identification aids in the diagnosis of measles and provides epidemiological information on measles. Measles is an acute, highly infectious disease, particularly in children, characterized by a confluent and blotchy rash.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that rubeola virus serological reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel recognizes that a definitive diagnosis of rubeola virus infections by serological methods is often retrospective since the patient generally recovers from the illness before the serodiagnosis can be made. The Panel also notes that there is no specific treatment at this time for the disease(s) (i.e., there is a lack of available antiviral drug therapy). Consequently, the risk of an incorrect diagnosis relates primarily to the dissemination of infection to other individuals or communities. The Panel members have noted variation in the manufacture of these reagents as to their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedure can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and on a history of satisfactory performance of the devices.

5. Risks to health: Epidemiological misinformation: Failure of the device to detect the presence of rubeola viruses may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates primarily to the dissemination of infection to other individuals or communities.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that rubeola virus serological reagents be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3520, to read as follows:

§ 866.3520 Rubeola (measles) virus serological reagents.

(a) *Identification.* Rubeola (measles) virus serological reagents are devices that consist of antigens and antisera used in serological tests to identify rubeola (measles) virus antibodies in a patient's serum. The identification aids in the diagnosis of measles and provides epidemiological information on measles. Measles is an acute, highly infectious disease, particularly in children, characterized by a confluent and blotchy rash.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administation, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m, Monday through Friday.

Dated: March 7, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11810 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2194]

Medical Devices; Classification of Salmonella spp. Serological Reagents

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Salmonella* ssp. serological reagents into class II (performance standard). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that these

devices be classified into class II with the exception of *Salmonella* ssp. immunofluorescent reagents and *Salmonella* spp. antigens, both of which the Panel recommended be classified into class I (general controls). The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. The effect of classifying a device into class II is to provide for future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910. 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classificaiton of Salmonella spp. serological reagents:

1. Identification: *Salmonella* spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Salmonella* spp. from cultured isolates derived from clinical specimens. Additionally, some of these reagents consist of antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to directly identify *Salmonella* spp. from clinical specimens and/or cultured isolates derived from clinical specimens. The identification aids in the diagnosis of salmonellosis caused by bacteria belonging to the genus *Salmonella* and provides epidemiological information on this disease. Salmonellosis is characterized by high grade fever ("enteric fever"), severe diarrhea, and cramps.

2. Recommended classification: The Microbiology Device Classification Panel recommends that *Salmonella* spp. serological reagents (antisera only) be classified into class II (performance standards) and that establishing a performance standard for this device be a medium priority. The Panel also recommends that *Salmonella* spp. immunofluorescent reagents and *Salmonella* spp. antigens be classified into class I (general controls) and that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that *Salmonella* spp. serological reagents (antisera only) be classified into class II because there is need for a performance standard that prescribes for these devices acceptable ranges of titer, sensitivity, and specificity and thereby minimizes the possibility that the devices may generate inaccurate diagnositic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Evins, Linne, and Colvin (Ref. 1) evaluated *Salmonella* spp. antisera from six commercial producers. Center for Disease Control (CDC) methods and specifications were used. Results of this study showed that six antisera did not meet CDC performance specifications. Additional data (unpublished) from the CDC's premarket evaluation program for the calendar years 1971 through 1975 demonstrate the variability of these reagents intended to meet CDC specifications (Ref. 2). Forty-five different lots of commercial *Salmonella* somatic antisera were recently evaluated by the CDC, of which 20 percent were found unacceptable. CDC methods and specifications were used in this evaluation (Ref. 3). The clinical experience of the Panel members and their familiarity with the literature have disclosed appreciable variation in the manufacture of *Salmonella* spp. antisera regarding their sensitivity, specificity, and titer (Refs. 1 through 4). The Panel is aware of the availability of reference materials, performance specifications, and evaluation methods for these reagents (Ref. 4). The Panel believes that general controls would not provide sufficient control over the device's titer, sensitivity, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard. The Panel further recommends that *Salmonella* spp. antigens and immunofluorescent reagents be classified into class I because the Panel believes general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel members noted variation in the manufacture of these reagents regarding their sensitivity, specificity, and titer. The Panel believes, however, that any variation in the sensitivity, specificity, and titer of these reagents resulting from manufacturing procedures can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which is the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and upon a review of the literature (Refs. 1 through 11).

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the devices to perform satisfactorily may lead to an error in the diagnosis of diseases caused by *Salmonella* spp. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of *Salmonella* spp. may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the disseminiation of infections to other individuals or communities.

Proposed Classification

FDA agrees with the Panel recommendation with respect to *Salmonella* spp. serological reagents (excluding antigens and immunofluorescent reagents) and is proposing that these devices be classified into class II (performance standards). However, FDA disagrees with the Panel recommendation with respect to *Salmonella* spp. antigens and *Salmonella* spp. immunofluorescent reagents and is proposing that these devices be classified into class II (performance standards). The agency has reviewed the Panel recommendation to classify these two groups of devices into class I and has sought additional data and documentation on the safety and effectiveness of these devices. The agency has reviewed the available literature pertaining to antigens and immunofluorescent reagents. The agency recognizes that the performance characteristics of *Salmonella* spp. serological reagents, including *Salmonella* spp. antigens and immunofluorescent reagents, depends appreciably on how they are manufactured. The agency notes that *Salmonella* spp. antigens and immunofluorescent reagents are produced using essentially the same manufacturing procedures as those for the serological reagents consisting of antisera discussed herein. Therefore, the agency is proposing that *Salmonella* spp. antigens and immunofluorescent reagents be classified into class II (performance standards).

The agency believes that a performance standard is necessary for *Salmonella* spp. serological reagents because general controls alone are insufficient to control the risks to health presented by these devices. A performance standard would provide reasonable assurance of the safety and effectiveness of the devices. The agency believes that there is sufficient information to establish a performance standard for these devices (Ref. 4).

References

The following information has been placed in the office of the Hearing Clerk and may be seen by interested persons,

from 9 a.m. to 4 p.m., Monday through Friday.

1. Evins, G. M., L. L. Linne, and H. M. Colvin, "Evaluation of Commercial *Salmonella* O Polyvalent and Vi Antisera," *Journal of Clinical Microbiology*, 4:349–353, 1976.

2. Results of a Five Year (1971–1975) Premarket Evaluation Program for Commercial Microbiological Diagnostic Products, Center for Disease Control, Public Health Service, Department of Health, Education, and Welfare, (unpublished).

3. Evins, G. M., L. L. Linne, and H. M. Colvin, "Assessment of Availability and Efficacy of Commercial *Salmonella* Grouping Antisera," *Journal of Clinical Microbiology*, 8(4):360–368, 1978.

4. "Specifications and Evaluation Methods for Immunological and Microbiological Reagents, Volume 1," 4th Ed., Center for Disease Control, Public Health Service, Department of Health, Education, and Welfare, B11–15–24, 1975.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3550, to read as follows:

§ 866.3550 Salmonella spp. serological reagents.

(a) *Identification. Salmonella* spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Salmonella* spp. from cultured isolates derived from clinical specimens. Additionally, some of these reagents consist of antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to directly identify *Salmonella* spp. from clinical specimens and/or cultured isolates derived from clinical specimens. The identification aids in the diagnosis of salmonellosis caused by bacteria belonging to the genus *Salmonella* and provides epidemiological information on this disease. Salmonellosis is characterized by high grade fever ("enteric fever"), severe diarrhea, and cramps.

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 7, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11811 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2197]

Medical Devices; Classification of Schistosoma spp. Serological Reagents

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Schistosoma* spp. serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATE: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register**.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elswhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of *Schistosoma* spp. serological reagents:

1. Identification: *Schistosoma* spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Shistosoma* spp. antibodies in a patient's serum. The identification aids in the diagnosis of schistosomiasis caused by parasitic flatworms of the genus *Schistosoma*. Schistosomiasis is characterized by a variety of acute and chronic infections. Acute infection is marked by fever, allergic symptoms, and diarrhea. Chronic effects are usually severe and are caused by fibrous degeneration of tissue around deposited eggs of the parasite in the liver, lungs, and central nervous system. Schistosomes can also cause schistosome dermatitis (e.g., swimmer's itch), a skin disease marked by intense itching.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that *Schistosoma* spp. serological reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. Serological testing is often the method of choice for the diagnosis of schistosomiasis. The Panel members have noted variation in the manufacture of these reagents with respect to their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedure can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of these reagents to perform satisfactorily may lead to an error in the diagnosis of schistosomiasis. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that *Schistosoma* spp. serological reagents be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3600, to read as follows:

§ 866.3600 Schistosoma spp. serological reagents.

(a) *Identification. Schistosoma* spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Schistosoma* spp. antibodies in a patient's serum. The identification aids in the diagnosis of schistosomiasis caused by parasitic flatworms of the genus *Schistosoma.* Schistosomiasis is characterized by a variety of acute and chronic infections. Acute infection is marked by fever, allergic symptoms, and diarrhea. Chronic effects are usually severe and are caused by fibrous degeneration of tissue around-deposited eggs of the parasite in the liver, lungs, and central nervous system. Schistosomes can also cause schistosome dermatitis (e.g., swimmer's itch), a skin disease marked by intense itching.

(b) *Classification:* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11812 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2198]

Medical Devices; Classification of Serratia spp. Serological Reagents

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Serratia* spp. serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of *Serratia* spp. serological reagents:

1. Identification: *Serratia* spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Serratia* spp. from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus *Serratia* and provides epidemiological information on these diseases. *Serratia* spp. are occasionally associated with gastroenteritis (food poisoning) and wound infections.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that *Serratia* spp. serological reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel members have noted variation in the manufacture of these reagents as to their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedure can adequately be controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of diseases caused by *Serratia* spp. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of *Serratia* spp. may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that *Serratia* spp. serological reagents be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a) , 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3630, to read as follows:

§ 866.3630 . Serratia spp. serological reagents.

(a) *Identification. Serratia* spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Serratia* spp. from cultured isolates. The identification aids in the diagnosis of disease cause by bacteria belonging to the genus *Serratia* and provides epidemiological information on these diseases. *Serratia* spp. are occasionally associated with gastroenteritis (food poisoning) and wound infections.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-11813 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 866

[Docket No. 78N-2199]

Medical Devices; Classification of Shigella spp. Serological Reagents

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Shigella* spp. serological reagents into class II (performance standards). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of *Shigella* spp. serological reagents:

1. Identification: *Shigella* spp. serological reagents are devices that consist of antigens and antisera, including antisera conjugated with a fluorescent dye (immunofluorescent reagents), used in serological tests to identify *Shigella* spp. from cultured isolates. The identification aids in the diagnosis of shigellosis caused by bacteria belonging to the genus *Shigella* and provides epidemiological information on this disease. Shigellosis is characterized by abdominal pain, cramps, diarrhea, and fever.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that *Shigella* spp. serological reagents be classified into class II because there is a need for a performance standard that prescribes for these devices acceptable ranges of titer, sensitivity, and specificity and thereby minimizes the possibility that the devices may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel recognizes certain serological groups of *Shigella* are more infectious than other groups. Consequently, serological identification of *Shigella* spp. isolates is particularly important for epidemiological information on *Shigella* spp. The Panel believes that general controls would not provide sufficient control over the devices' titer, sensitivity, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the devices and that there is sufficient information to establish a standard. The clinical experience of the Panel members has disclosed appreciable variation in the manufacture of these reagents as to their sensitivity, specificity, and titer. The Panel is aware of the availability of reference materials, performance specifications and evaluation methods for these reagents (Ref. 1).

4. Summary of the data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and upon a review of the literature (Ref. 1).

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of shigellosis. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of *Shigella* spp. may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that *Shigella* spp. serological reagents be classified into class II (performance standards). The agency believes that a performance standard is necessary for these devices because general controls alone are insufficient to control the risks to health presented by the devices. A performance standard would provide reasonable assurance of the safety and effectiveness of the devices. The agency believes that there is sufficient information to establish a performance standard for these devices.

References

The following information has been places in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. "Specifications and Evaluation Methods for Immunological and Microbiological Reagents," Vol. 1, 4th Ed., Center for Disease Control, Public Health Service, Department of Health, Education, and Welfare, B11-25-28, 1975.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3660, to read as follows:

§ 866.3660 Shigella spp. serological reagents.

(a) *Identification. Shigella* spp. serological reagents are devices that consist of antigens and antisera, including antisera conjugated with a fluorescent dye (immunofluorescent reagents), used in serological tests to identify *Shigella* spp. from cultural isolates. The identification aids in the diagnosis of shigellosis caused by bacteria belonging to the genus *Shigella* and provides epidemiological information on this disease. Shigellosis is characterized by abdominal pain, cramps, diarrhea, and fever.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-11814 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 866

[Docket No. 78N-2200]

Medical Devices; Classification of Sporothrix Schenckii Serological Reagents

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Sporothrix schenckii* serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of *Sporothrix schenckii* serological reagents:

1. Identification: *Sporothrix schenckii* serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Sporothrix schenckii* antibodies in a patient's serum. The identification aids in the diagnosis of sporothrichosis caused by a fungus belonging to the genus *Sporothrix* and provides epidemiological information on this disease. Sporothrichosis is a chronic tumorlike infection primarily of the skin.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that *Sporothrix schenckii* serological reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel believes that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedure can be adequately controlled by manufacturer compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of sporothrichosis. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of *Sporothrix schenckii* may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that *Sporothrix schenckii* serological reagents be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3680, to read as follows:

§ 866.3680 Sporothrix schenckii serological reagents.

(a) *Identification. Sporothrix schenckii* serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Sporothrix schenckii* antibodies in a patient's serum. The identification aids in the diagnosis of sporothrichosis caused by a fungus belonging to the genus *Sporothrix* and provides epidemiological information on this disease. Sporothrichosis is a chronic tumorlike infection primarily of the skin.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-11815 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 866

[Docket No. 78N-2201]

Medical Devices; Classification of Staphylococcus Aureus Serological Reagents

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Staphylococcus aureus* serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of *Staphylococcus aureus* serological reagents:

1. Identification: *Staphylococcus aureus* serological reagents are devices that consist of antigens and antisera used in serological tests to identify enterotoxin (toxin affecting the intestine) producing staphylococci from cultured isolates derived from food sources. The identification aids in the diagnosis of disease caused by this bacteria belonging to the genus *Staphylococcus* and provides epidemiological information on these diseases. Certain strains of *Staphylococcus aureus* produce an enterotoxin while growing in meat, dairy, or bakery products. After ingestion, this enterotoxin is absorbed in the gut and causes destruction of the intestinal lining (gastroenteritis).

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that *Staphylococcus aureus* serological reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel has noted variation in the manufacture of these reagents regarding their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedure can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of staphylococcal gastroenteritis. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of enterotoxin producing *Staphylococcus aureus* may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that *Staphylococcus aureus* serological reagents be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3700, to read as follows:

§ 866.3700 Staphylococcus aureus serological reagents.

(a) *Identification. Staphylococcus aureus* serological reagents are devices that consist of antigens and antisera used in serological tests to identify enterotoxin (toxin affecting the intestine) producing staphylococci from cultured isolates. The identification aids in the diagnosis of disease caused by this bacterium belonging to the genus *Staphylococcus* and provides epidemiological information on these diseases. Certain strains of *Staphylococcus aureus* produce an enterotoxin while growing in meat, dairy, or bakery products. After ingestion, this enterotoxin is absorbed in the gut and cause destruction of the intestinal lining (gastroenteritis).

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11816 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

21 CFR Part 866

[Docket No. 78N–2202]

Medical Devices; Classification of Streptococcus spp. Exoenzyme Reagents

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Streptococcus* spp. exoenzyme reagents into class II (performance standards). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of *Streptococcus* spp. exoenzyme reagents:

1. Identification: *Streptococcus* spp. exoenzyme reagents are devices used in serological tests to identify *Streptococcus* spp. exoenzyme antibodies in a patient's serum. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus *Streptococcus* and provides epidemiological information on these diseases. Pathogenic streptococci are associated with infections, such as sore throat, impetigo (an infection characterized

by small pustules on the skin), urinary tract infections, rheumatic fever, and kidney disease.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that *Streptococcus* spp. exoenzyme reagents be classified into class II because there is a need for a performance standard that prescribes for these devices acceptable ranges of titer, sensitivity, and specificity and thereby minimizes the possibility that the devices may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Many pathogenic streptococci produce and secrete several enzymes (antigens) which induce antibody responses. Serological tests are often used to detect increased levels of these antibodies as an aid in the diagnosis of streptococcal infection. The clinical experience of the Panel members and their familiarity with the literature has disclosed appreciable lot-to-lot variation in the manufacture of these reagents with respect to their sensitivity, specificity, and titer (Refs. 1, 2, and 3). Klein and Jones (Ref. 1) compared a multi-enzyme streptozyme test with three individual streptococcal exoenzyme tests, antistreptolysin O (ASO), antideoxyribonuclease B (ADN–B) and antihyaluronidase (AH) and observed that the multi-enzyme test is less sensitive for ADN–B than ASO antibodies. Klein and Jones also observed that the multi-enzyme streptozyme test is less sensitive for multiple antibodies ASO, ADN–B, and AH than are a combination of the conventional ASO, ADN–B, and AH tests. Golubjatnikov, et al. (Ref. 2) compared the streptococcal multi-enzyme test with the conventional ASO and ADN–B tests and observed a low rate of agreement among these tests. Golubjatnikov, et al. also suggested that the upper limits for normal ADN–B titers used by manufacturers of the ADB test kits are too low, indicating standards should be developed to provide normal ranges for the streptococcal enzyme tests. Hederstedt, et al. (Ref. 3) also compared the multi-enzyme test to the ADN–B and AH test and observed considerable discrepancies in the results. Hederstedt, et al. concluded that stricter control of lot-to-lot variations and standardization of the multi-enzyme test reagent is required. The Panel noted that an international standard for Antistreptolysin O has been established (Ref. 4) and could serve as the basis for a performance standard. The Panel believes that general controls would not provide sufficient control over the devices' titer, sensitivity, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the devices and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1 through 4).

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of diseases caused by *Streptococcus* spp. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of *Streptococcus* spp. exoenzyme antibody may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that the *Streptococcus* spp. exoenzyme reagents be classified into class II (performance standards). The agency believes that a performance standard is necessary for these devices because general controls along are insufficient to control the risks to health presented by these devices. A performance standard would provide reasonable assurance of the safety and effectiveness of the devices. The agency believes that there is sufficient information to establish a performance standard for these devices.

References

The following information has been placed in the office of the Hearing Clerk and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Klein, G. C. and W. L. Jones, "Comparison of the Streptozyme Test with the Antistreptolysin O, Antideoxyribonuclease B, and Antihyaluronidase Tests," *Applied Microbiology*, 21:257–259, 1971.

2. Golubjatnikov, R., J. E. Koehler, and J. Buccowich, "Comparative Study of Antistreptolysin O, Antideoxyribonuclease B, and Multienzyme Tests in Streptococcal Infections," *Health Laboratory Science*, 14(4): 284–290, 1977.

3. Hederstedt, B., S. E. Holm, and T. Wadstrom, "Discrepancy Between Results of the Streptozyme Test and Those of the Antideoxyribonuclease B, and Antihualuronidase Tests," *Journal of clinical Microbiology*, 8:50–53, 1978.

4. Spaun, J., M. W. Bentzon, S.O. Larsen, and L. F. Hewitt, "International Standard for Antistreptolysin-O," *Bullentin of the World Health Organization*, 24:271–279, 1961.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3720, to read as follows:

§ 866.3720 Streptococcus spp. exoenzyme reagents.

(a) *Identification. Streptococcus* spp. exoenzyme reagents are devices used to identify *Streptococcus* spp. exoenzyme antibodies in a patient's serum. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus *Streptococcus* and provides epidemiological information on these diseases. Pathogenic streptococci are associated with infections, such as sore throat, impetigo (an infection characterized by small pustules on the skin), urinary tract infections, rheumatic fever, and kidney disease.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm, 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc 80–11817 Filed 4–21–80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 866

[Docket No 78N–2203]

Medical Devices; Classification of Streptococcus spp. Serological Reagents

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Streptococcus* spp. serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into Class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATE: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of this publication in the **Federal Register.**

ADDRESS: Written comments to the Office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of *Streptococcus* spp. serological reagents:

1. Identification: *Streptococcus* spp. serological reagents are devices that consist of antigens and antisera (excluding streptococcal exoenzyme reagents made from enzymes secreted by streptococci) used in serological tests to identify *Streptococcus* spp. from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of diseases caused by bacteria belonging to the genus *Streptococcus* and provides epidemiological information on these diseases. Pathogenic streptococci are associated with infections, such as sore throat, impetigo (an infection characterized by small pustules on the skin), urinary tract infections, and with allergic-type reactions such as rheumatic fever, and kidney disease.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that *Streptococcus* spp. serological reagents be classified into class I because the Panel believes general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel has noted variation in the manufacture of these reagents with respect to their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedure can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of diseases caused by *Streptococcus* spp. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of *Streptococcus* spp. may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that *Streptococcus* spp. serological reagents be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3740, to read as follows:

§ 866.3740 Streptococcus spp. serological reagents.

(a) *Identification. Streptococcus* spp. serological reagents are devices that consist of antigens and antisera (excluding streptococcal exoenzyme reagents made from enzymes secreted by streptococci) used in serological tests to identify *Streptococcus* spp. from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of diseases caused by bacteria belonging to the genus *Streptococcus* and provides epidemiological information on these diseases. Pathogenic streptococci are associated with infections, such as sore throat, impetigo (an infection characterized by small pustules on the skin), urinary tract infections, and with allergic-type reactions, such as rheumatic fever, and kidney disease.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11818 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

21 CFR Part 866

[Docket No. 78N–2204]

Medical Devices; Classification of Toxoplasma Gondii Serological Reagents

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Toxoplasma gondii* serological reagents into class II (performance standards). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that these devices be classified into class II with the exception of *Toxoplasma gondii* immunofluorescent reagents which the Panel recommended be classified into class I (general controls). The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. The effect of classifying a device into class II is to provide for future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides

background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of *Toxoplasma gondii* serological reagents:

1. Identification: *Toxoplasma gondii* serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Toxoplasma gondii* antibodies in a patient's serum. Additionally, some of these reagents consist of antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify *Toxoplasma gondii* from clinical specimens. The identification aids in the diagnosis of toxoplasmosis caused by the parasitic protozoan *Toxoplasma gondii* and provides epidemiological information on this disease. Congenital toxoplasmosis is characterized by lesions of the central nervous system, which if undetected and untreated may lead to brain defects, blindness, and death of an unborn fetus. The disease is characterized in children by inflammation of the brain and spinal cord.

2. Recommended classification: The Microbiology Device Classification Panel recommends that *Toxoplasma gondii* serological reagents (excluding immunofluorescent reagents) be classified into class II (performance standards) and that establishing a performance standard for this device be a high priority. The Panel also recommends that *Toxoplasma gondii* immunofluorescent reagents be classified into class I (general controls) and that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that *Toxoplasma gondii* serological reagents (excluding immunofluorescent reagents) be classified into class II because there is a need for a performance standard that prescribes for these devices acceptable ranges of titer, sensitivity, and specificity and thereby minimizes the possibility that the devices may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Serodiagnosis is often the method of choice for a definitive diagnosis of toxoplasmosis. The clinical experience of the Panel members and their familiarity with the literature have disclosed appreciable lot-to-lot variation in the manufacture of these reagents regarding their sensitivity, specificity, and titer. The Panel is aware of the availability of reference materials, performance specifications, and evaluation methods for these reagents (Ref. 3). Remington (Ref. 1) tested the specificity of a number of commercial immunofluorescent reagents over a period of several years and observed appreciable variability. He advises laboratory personnel of the risk of obtaining false-positive and false-negative test results unless all commercial antisera are tested for specificity prior to use. Further, Remington strongly recommended that commercial antisera meet rigid standards of control for specificity and sensitivity. The Center for Disease Control (CDC) has performance specifications for commercial serological reagents and has been conducting voluntary premarket testing. Over a 6-year period only 49 percent of the products tested by CDC were found to be satisfactory (Ref. 3). Durham and Colvin (Ref. 2) report a decline in performance of immunofluorescent kits indicated by the decrease in the satisfactory incidence rate from 83.3 percent in 1973 to 31.6 percent in the first 6 months of 1977. The Panel believes that general controls would not provide sufficient control over the devices' titer, sensitivity, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectivenes of the devices and that there is sufficient information to establish a standard. The Panel further recommends that *Toxoplasma gondii* immunofluorescent reagents be classified into class I because the Panel believes general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel members noted variation in the manufacture of these reagents regarding their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedures can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and upon a review of the literature (Refs. 1, 2, and 3).

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of diseases caused by *Toxoplasma gondii*. Inappropriate therapy based on inaccurate diagnositic data may place the patient at risk. False-positive daga may result in treatment with a drug that possesses undesirable side effects; false-negative data, when the patient is an infant or pregnant woman, may prevent necessary treatment and result in damage to the infant or fetus. (b) Epidemiological misinformation: Failure of the device to detect the presence of *Toxoplasma gondii* may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

Proposed Classification

FDA agrees with the Panel recommendation with respect to *Toxoplasma gondii* serological reagents (excluding immunofluorescent reagents) and is proposing that these devices be classified into class II (performance standards). However, FDA disagrees with the Panel recommendation with respect to *Toxoplasma gondii* imunofluorescent reagents and is proposing that these devices be classified into class II (performance standards). The agency has reviewed the Panel recommendation to classify these devices into class I and has sought additional data and documentation on the safety and effectiveness of these devices. The agency has reviewed the available literature pertaining to immunofluorescent reagents. The agency recognizes that the performance characteristics of immunofluorescent reagents depends appreciably on how they are manufactured. The agency notes that immunofluorescent reagents are produced using essentially the same manufacturing procedures as those for the other serological reagents described herein. Therefore, the agency is proposing that *Toxoplasma gondii* immunofluorescent reagents be classified into class II (performance standards).

The agency believes that a performance standard is necessary for *Toxoplasma gondii* serological reagents because general controls alone are insufficient to control the risks to health presented by these devices. A performance standard would provide reasonable assurance of the safety and effectiveness of these devices. The agency also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of these devices (Ref. 3).

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons from 9 a.m. to 4 p.m., Monday through Friday.

1. Remington, J. S., "Toxoplasmosis in the Adult," *Bulletin of the New York Academy of Medicine*, 50(2): 211–227, 1974.

2. Durham, T. M. and H. M. Colvin, "Premarket Evaluation of Commercial Toxoplasmosis Indirect Fluorescent Antibody Reagents," *Journal of Clinical Microbiology*, 7(3): 255–260, 1978.

3. *Specifications and Evaluation Methods for Immunological and Microbiological Reagents*, Volume 1, 4th Ed., Center for Disease Control, Public Health Service, Department of Health, Education, and Welfare, C–20–23, 1975.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3780, to read as follows:

§ 866.3780 Toxoplasma gondii serological reagents.

(a) *Identification. Toxoplasma gondii* serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Toxoplasma gondii* antibodies in a patient's serum.

Additionally, some of these reagents consist of antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify *Toxoplasma gondii* from clinical specimens. The identification aids in the diagnosis of toxoplasmosis caused by the parasitic protozoan *Toxoplasma gondii* and provides epidemiological information on this disease. Congenital toxoplasmosis is characterized by lesions of the central nervous system, which if undetected and untreated may lead to brain defects, blindness, and death of an unborn fetus. The disease is characterized in children by inflammation of the brain and spinal cord.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11819 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2206]

Medical Devices; Classification of Treponema Pallidum Nontreponemal Test Reagents

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Treponema pallidum* nontreponemal test reagents into class II (performance standard). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. The actions are being taken under the Medical Device Amendments of 1976.

DATE: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of *Treponema pallidum* nontreponemal test reagents:

1. Identification: *Treponema pallidum* nontreponemal test reagents are devices that consist of antigens and antisera, which are derived from nontreponemal sources (sources not directly associated with treponemal organisms), and other control reagents (standardized reagents with which test results are compared) used to identify reagin, an antibody-like agent, which is produced from the reaction of treponemal microorganisms with certain body tissues. The identification aids in the diagnosis of syphilis caused by bacteria belonging to the genus *Trenponema* and provides epidemiological information on syphilis. Syphilis is a contagious veneral disease which can lead to many structural and skin-related lesions. It is transmitted by direct sexual contact or to a newborn by an infected mother (congenital syphilis).

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that *Treponema pallidum* nontreponemal test reagents be classified into class II because there is a need for a performance standard that prescribes for these devices acceptable ranges of titer, sensitivity, and specificity and thereby minimizes the possiblilty that the devices may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel observes that serological testing is presently the only available method for diagnosis of syphilis. The Center for Disease Control (CDC) has performance specifications and reference materials for nontreponemal test reagents. Since 1971 CDC has operated a premarket evaluation program for the voluntary testing of commercially available in vitro diagnostic products, including nontreponemal test reagents for syphilis. The results of the first 5 years (1971 through 1975) of testing demonstrates the variability of these reagents intended to meet CDC specifications (Ref. 1). Black (Ref. 2) reported significantly different sensitivities among three nontreponemal tests when compared to the fluorescent treponemal antibody absorption test (FTA–ABS, a definitive test for syphilis). The clinical experience of the Panel members and their familiarity with the literature have disclosed appreciable variation in the manufacture of these reagents with respect to their sensitivity, specificity, and titer (Refs. 1 and 2). The Panel is aware of the availability of reference materials, performance specifications, and evaluation methods for these reagents (Ref. 3). The causative bacterium is not capable of being cultivated by usual laboratory procedures. Diagnosis based on detection of reagin is regarded as presumptive for syphilis. The Panel believes that general controls would not provide sufficient control over the devices' titer sensitivity, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of devices and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and upon a review of the literature (Refs. 1, 2, and 3).

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of syphilis. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of *Treponema pallidum* may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that *Treponema pallidum* nontreponemal test reagents be classified into class II (performance standards). The agency believes that a performance standard is necessary for these devices because general controls alone are insufficient to control the risks to health presented by the devices. A performance standard would provide reasonable assurance of the safety and effectiveness of the devices. The agency believes that there is sufficient information to establish a performance for these devices.

1. Results of a Five Year (1971–1975) Premarket Evaluation Program for

Commercial Microbiology Diagnostic Products, Center for Disease Control, Public Health Service, Department of Health, Education, and Welfare, (unpublished).

2. Black, D. A., P. E. Ray, and B. L. Therrell, "Quantitative Evaluation of the Reagin Screen Test," *Journal of Clinical Microbiology*, pp. 16–18, July 1976.

3. *Specifications and Evaluation Methods for Immunological and Microbiological Reagents, Vol. 1*, 4th Ed., Center for Disease Control, Public Health Service, Department of Health, Education, and Welfare, BIII–5, 1975.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3820, to read as follows:

§ 866.3820 Treponema pallidum nontreponemal test reagents.

(a) *Identification. Treponema pallidum* nontreponemal test reagents are devices that consist of antigens derived from nontreponemal sources (sources not directly associated with treponemal organisms) and control sera (standardized sera with which test results are compared) used in serological tests to identify reagin, an antibody-like agent, which is produced from the reaction of treponeme microorganisms with body tissues. The identification aids in the diagnosis of syphilis caused by microorganisms belonging to the genus *Treponema* and provides epidemiological information on syphilis.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m. Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11820 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

21 CFR Part 866

[Docket No. 78N–2207]

Medical Devices; Classification of Treponema Pallidum Treponemal Test Reagents

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Treponema pallidum* treponemal test reagents into class II (performance standards). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of *Treponema pallidum* treponemal test reagents:

1. Identification: *Treponema pallidum* treponemal test reagents are devices that consist of the antigens, antisera and all control reagents (standardized reagents with which tests results are compared) which are derived from treponemal sources and that are used in the fluorescent treponemal antibody absorption test (FTA–ABS), the *Treponema pallidum* immobilization test (T.P.I.), and other treponemal tests used to identify treponemal antibodies (antibodies induced directly from infecting treponemal organisms) in a patient's serum. The identification aids in the diagnosis of syphilis caused by bacteria belonging to the genus *Treponema* and provides epidemiological information on syphilis. Syphilis is a contagious venereal disease which can lead to many structural and skin-related lesions. It is transmitted either by direct sexual contact or to a newborn by an infected mother (congenital syphilis).

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for Panel recommendation: The Panel recommends that *Treponema pallidum* treponemal test reagents be classified into class II because there is a need for a performance standard that prescribes for these devices acceptable ranges of titer, sensitivity, and specificity and thereby minimizes the possibility that the devices may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily.

Procedures for evaluating the fluorescein-labeled anti-human globulin (antibody to human antibody labeled with fluorescein) for the FTA–ABS test have been established (Ref. 1). Hardy (Ref. 2) and Hunter (Ref. 3) have indicated that variation occurs in anti-human conjugate preparations that could affect test results. Cherry, et al. (Ref. 4) examined the purity of commercial preparations from 12 sources of fluorescein isothiocyanate (a fluorescent dye) used for the FTA–ABS test and observed that the purity was highly variable. Scales, Jacobs, and Skaggs reported undesirable immunological specificity in commercial conjugates (Ref. 5). Cherry and Reimer included anti-human globulins as major immunofluorescent reagents requiring a high priority for standardization (Ref. 6). CDC has performance specifications and reference materials for treponemal test reagents. Since 1971, CDC has operated a premarket evaluation program for the voluntary testing of commercially available diagnostic products, including treponemal test reagents. The results of the first 5 years (1971 through 1975) of testing demonstrate the variability of these reagents, some of which do not meet CDC specifications (Ref. 7).

The causative bacterium is not cultivatable by usual laboratory procedures. Diagnosis based on detection of treponemal antibodies is regarded as definitive for syphilis.

The clinical experience of the Panel members and their familiarity with the literature have disclosed appreciable variation in the manufacture of these reagents as to their sensitivity, specificity, and titer (Refs. 2 through 7).

The Panel believes that general controls would not provide sufficient control over the device's titer, sensitivity, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard. The Panel is aware of

the availability of reference materials, performance specifications, and evaluation methods for these reagents (Ref. 8).

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1 through 8).

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the devices to perform satisfactorily may lead to an error in the diagnosis of syphilis. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of *Treponema pallidum* may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that the *Treponema pallidum* treponemal test reagents be classified into class II (performance standards). The agency believes that a performance standard is necessary for these devices because general controls alone are insufficient to control the risks to health presented by the devices. A performance standard would provide reasonable assurance of the safety and effectiveness of the devices. The agency believes that there is sufficient information to establish a performance standard for these devices.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. *Manual of Tests for Syphilis*, U.S. Department of Health, Education, and Welfare, Public Health Service, National Communicable Disease Center, Venereal Disease Program, Atlanta, GA, Pub. No. 411, 1969.

2. Hardy, P., H. and E. E. Nell, "Characteristics of Fluorescein Labelled Antiglobulin Preparations That May Affect the Fluorescent Treponemal Antibody-Absorption Test," *American Journal of Clinical Pathology*, 56:181–186, 1971.

3. Hunter, E. F., J. F. Smith, J. S. Lewis, B. E. McGrew, and J. D. Schmale, "Immunochemical Parameters of Some Commerical Conjugates for the Fluorescent Treponemal Antibody-Absorption Test," *Infection and Immunity*, 5:858–862, 1972.

4. Cherry, W. B., R. M. McKinney, V. M. Emmel, J. T. Spillane, G. A. Hebert, and B. Pittman, "Evaluation of Commercial Fluorescein Isothiocynates Used in Fluorescent Antibody Studies," *Stain Technology*, 44(4):179–186, 1969.

5. Scales, R. W., N. F. Jacobs, Jr., and R. Skaggs, "Use of Immunoglobulin Coupled to Agarose Beads for Examining the Specificity of Conjugates," *Journal of Clinical Microbiology*, 2(4):292–295, 1975.

6. Cherry, W. B. and C. B. Reimer, "Standardization of Diagnostic Materials, 4. Diagnostic Immunofluorescence," *World Health Organization Bulletin*, 48:737–745, 1973.

7. Results of a Five-Year (1971–1975) Premarket Evaluation Program for Commercial Microbiological Diagnostic Products, Center for Disease Control, Public Health Service, Department of Health, Education, and Welfare, (unpublished).

8. *Specifications and Evaluation Methods for Immunological and Microbiological Reagents, Vol. 1*, 4th Ed., Center for Disease Control, Public Health Service, Department of Health, Education, and Welfare, BIII–1–11, 1974.

Therefore, under the Federal Food, Drug, Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3830, to read as follows:

§ 866.3830 Treponema pallidum treponemal test reagents.

(a) *Identification. Treponema pallidum* treponemal test reagents are devices that consist of antigens, antisera and all control reagents (standardized reagents with which tests results are compared) which are derived from treponemal sources and that are used in the fluorescent treponemal antibody absorption test (FTA–ABS), the *Treponema pallidum* immobilization test (T.P.I.), and other treponemal tests used to identify treponemal antibodies (antibodies induced directly from infecting treponemal organisms) in a patient's serum. The identification aids in the diagnosis of syphilis caused by bacteria belonging to the *Treponema* and provides epidemiological information on syphilis. Syphilis is a contagious veneral disease which can lead to many structural and skin-related lesions. It is transmitted either by direct sexual contact or to a newborn by an infected mother (congenital syphilis).

(b) *Classification:* Class II (performance standards).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-11821 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 866

[Docket No. 78N-2208]

Medical Devices; Classification of Trichinella Spiralis Serological Reagents

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Trichinella spiralis* serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of *Trichinella spiralis* serological reagents:

1. Identification: *Trichinella spiralis* serological reagents are devices that consist

of antigens and antisera used in serological tests to identify *Trichinella spiralis* antibodies in a patient's serum. The identification aids in the diagnosis of trichinosis caused by parasitic roundworms belonging to the genus *Trichinella* and provides epidemiological information on trichinosis. Trichinosis is caused by ingestion of undercooked, infested meat, especially pork, and characterized by fever, muscle weakness, and diarrhea.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that *Trichinella spiralis* serological reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel notes variation in the manufacture of these reagents as to their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedure can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and on a history of satisfactory performance of the devices.

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of trichinosis. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of *Trichinella spiralis* may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that *Trichinella spiralis* serological reagents be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3850, to read as follows:

§ 866.3850 Trichinella spiralis serological reagents.

(a) *Identification. Trichinella spiralis* serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Trichinella spiralis* antibodies in a patient's serum. The identification aids in the diagnosis of trichinosis caused by parasitic roundworms belonging to the genus *Trichinella* and provides epidemiological information on trichinosis. Trichinosis is caused by ingestion of undercooked, infested meat, especially pork, and characterized by fever, muscle weakness, and diarrhea.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11822 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2209]

Medical Devices; Classification of Trypanosoma spp. Serological Reagents

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Trypanosoma* spp. serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATE: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification *Trypanosoma* spp. serological reagents:

1. Indentification: *Trypanosoma* spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Trypanosoma* spp. antibodies in a patient's serum. The identification aids in the diagnosis of trypanosomiasis, a disease caused by parasitic protozoans belonging to the genus *Trypanosoma.* Trypanosomiasis in adults is a chronic disease characterized by fever, chills, headache, and vomiting. Central nervous system involvement produces typical sleeping sickness syndrome: physical exhaustion, inability to eat, tissue wasting, and eventual death. Chagas disease, an acute form of trypanosomiasis in children, most seriously affects the central nervous system and heart muscle.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that *Trypanosoma* spp. serological reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. Serological testing is often the preferred method for diagnosis of trypanosomiasis. The Panel notes variation in the manufacture of these reagents as to their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedure can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and on a history of satisfactory performance of the devices.

5. Risks to Health: Misdiagnosis and inappropriate therapy: Failure of the device

to perform satisfactorily may lead to an error in the diagnosis of trypanosomiasis. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that *Trypanosoma* spp. serological reagents be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3870, to read as follows:

§ 866.3870 Trypanosoma spp. serological reagents.

(a) *Identification. Trypanosoma* spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Trypanosoma* spp. antibodies in a patient's serum. The identification aids in the diagnosis of trypanosomiasis, a disease caused by parasitic protozoans belonging to the genus *Trypanosoma*. Trypanosomiasis in adults is a chronic disease characterized by fever, chills, headache, and vomiting. Central nervous system involvement produces typical sleeping sickness syndrome: physical exhaustion, inability to eat, tissue wasting, and eventual death. Chagas disease, an acute form of trypanosomiasis in children, most seriously affects the central nervous system and heart muscle.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11823 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2210]

Medical Devices; Classification of Varicella-Zoster Serological Reagents

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying varicella-zoster serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of varicella-zoster serological reagents:

1. Identification: Varicella-zoster serological reagents are devices that consist of antigens and antisera used in serological tests to identify varicella-zoster antibodies in a patient's serum. The identification aids in the diagnosis of diseases caused by varicella-zoster viruses and provides epidemiological information on these diseases. Varicella (chicken pox) is a mild, highly infectious disease, chiefly of children. Zoster (shingles) is the recurrent form of the disease, occurring in adults who were previously infected with varicella-zoster viruses. Zoster is the response (characterized by a rash) of the partially immune host to a reactivation of varicella viruses present in latent form in the patient's body.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that varicella-zoster serological reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel recognizes that a definitive diagnosis of varicella-zoster infection by serological methods is often retrospective since the patient generally recovers from the illness before the serodiagnosis can be made. The Panel also notes that there is currently no specific treament for the disease (i.e., there is a lack of available antiviral drug therapy). Consequently, the risk of an incorrect diagnosis relates primarily to the dissemination of infection to other individuals or communities. The Panel notes variation in the manufacture of these reagents as to their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedure can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and on a history of satisfactory performance of the devices.

5. Risks to health: Epidemiological misinformation: Failure of the device to detect the presence of varicella-zoster viruses may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that varicella-zoster serological reagents be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs

proposes to amend Part 866 in Subpart D by adding new § 866.3900, to read as follows:

§ 866.3900 Varicella-zoster serological reagents.

(a) *Identification.* Varicella-zoster serological reagents are devices that consist of antigens and antisera used in serological tests to identify varicella-zoster antibodies in a patient's serum. The identification aids in the diagnosis of diseases caused by varicella-zoster viruses and provides epidemiological information on these diseases. Varicella (chicken pox) is a mild, highly infectious disease, chiefly of children. Zoster (shingles) is the recurrent form of the disease, occurring in adults who were previously infected with varicella-zoster viruses. Zoster is the response (characterized by a rash) of the partially immune host to a reactivation of varicella viruses present in latent form in the patient's body.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11824 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

[21 CFR Part 866]

[Docket No. 78N–2211]

Medical Devices; Classification of Vibrio Cholerae Serological Reagents

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Vibrio cholerae* serological reagents into class II (performance standards). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information cond-cerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of *Vibrio cholerae serological reagents:*

1. Identification: *Vibrio cholerae* serological reagents are devices that are used in the agglutination (an antigen-antibody clumping reaction) test to identify *Vibrio cholerae* from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of cholera caused by the bacterium *Vibrio cholerae* and provides epidemiological information on cholera. Cholera is an acute infectious disease characterized by severe diarrhea with extreme fluid and electrolyte (salts) depletion, and by vomiting, muscle cramps, and prostration. If untreated, the severe dehydration may lead to schock, renal failure, cardiovascular collapse, and death.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that *Vibrio cholerae* serological reagents be classified into class II because there is a need for a performance standard that prescribes for these devices acceptable ranges of titer, sensitivity, and specificity and thereby minimizes the possibility that the devices may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Serological (agglutination) tests are often used to differentiate *Vibrio cholerae* from noncholera vibrios obtained from cultured isolates. The clinical experience of the Panel members has disclosed appreciable variation in the manufacture of these reagents regarding their sensitivity, specificity, and titer. The Panel believes that general controls would not provide sufficient control over the device's titer, sensitivity, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard. The Panel is aware of the availability of reference materials, performance specifications, and evaluation methods for these reagents (Ref. 1).

4. Summary of the data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Ref. 1).

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of cholera. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of *Vibrio cholerae* may contribute to epidemiological misinformation. Consequently, the risk of an incorrct diagnosis relates to the dissemination of infection to other individuals or communities.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that *Vibrio cholerae* serological reagents be classified into class II (performance standards). The agency believes that a performance standard is necessary for these devices because general controls alone are insufficient to control the risks to health presented by the devices. A performance standard would provide reasonable assurance of the safety and effectivenes of the devices. The agency believes that there is sufficient information to establish a performance standard for these devices.

References

The following information has been placed in the office of the Hearing Clerk (address above), and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. "Specifications and Evaluation Methods for Immunological and Microbiological Reagents," Vol. 1, 4th Ed., Center for Disease Control, Public Health Service, Department of Health, Education, and Welfare, B1–29–30, 1975.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the

Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3930, to read as follows:

§ 866.3930 Vibrio cholerae serological reagents.

(a) *Identification. Vibrio cholerae* serological reagents are devices that are used in the agglutination (an antigen-antibody clumping reaction) test to identify *Vibrio cholerae* from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of cholera caused by the bacterium *Vibrio cholerae* and provides epidemiological information on cholera. Cholera is an acute infectious disease characterized by severe diarrhea with extreme fluid and electrolyte (salts) depletion, and by vomiting, muscle cramps, and prostration. If untreated, the severe dehydration may lead to shock, renal failure, cardiovascular collapse, and death.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11825 Filed 4–21–80: 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2212]

Medical Devices; Classification of Complement Reagents

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying complement reagents into class I (general controls). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of complement reagents:

1. Identification: A complement reagent is a device that consists of naturally occurring serum protein from any warm-blooded animal (such as guinea pigs) that may be included as a component part of serological test kits used in the diagnosis of disease.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)).

3. Summary of reasons for recommendation: The Panel recommends that complement reagents be classified into class I because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel recommends that complement reagents be exempt from premarket notification procedures under section 510(k) of the act because the Panel believes that premarket notification is not necessary for the protection of the public health.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that complement reagents be classified into class I (general controls). The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

In response to the Panel's recommendation that manufacturers of a complement reagent be exempt from section 510(k) of the act (21 U.S.C. 360). FDA agrees with the Panel and is proposing that the manufacturer of this device be exempt from premarket notification under section 510(k) of the act and Subpart E of Part 807 of the regulations. The agency has determined that it is not necessary for the protection of the public health that FDA receive premarket notification submissions concerning a complement reagent. The agency does not at this time anticipate that premarket approval will be required for this device. The agency believes that the semiannual updating of device listing under section 510(j)(2) will provide FDA with adequate notice concerning new products within this generic type of device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 by adding new Subpart E and adding new § 866.4100, to read as follows:

Subpart E—Immunology Laboratory Equipment and Reagents

§ 866.4100 Complement reagent.

(a) *Identification.* A complement reagent is a device that consists of naturally occurring serum protein from any warm-blooded animal (such as guinea pigs) that may be included as a component part of serological test kits used in the diagnosis of disease.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in Subpart E of Part 807.

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-11826 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 866

[Docket No. 78N-2213]

Medical Devices; Classification of Immunoelectrophoresis Equipment

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying immunoelectrophoresis equipment into class I (general controls). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATE: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of this publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Srikrishna Vadlamudi, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of immunoelectrophoresis equipment:

1. Identification: Immunoelectrophoresis equipment for clinical use with its electrical power supply is a device used for separating protein molecules. Immunoelectrophoresis is a procedure in which a complex protein mixture is placed in an agar gel and the various proteins are separated on the basis of their relative mobilities under the influence of an electric current. The separated proteins are then permitted to diffuse through the agar toward a multispecific antiserum, allowing precipitation and visualization of the separate complexes.

2. Recommended classfication: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that immunoelectrophoresis equipment for clinical use be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that immunoelectrophoresis equipment be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart E by adding new § 866.4500, to read as follows:

§ 866.4500 Immunoelectrophoresis equipment.

(a) *Identification.* Immunoelectrophoresis equipment for clinical use with its electrical power supply is a device used for separating protein molecules. Immunoelectrophoresis is a procedure in which a complex protein mixture is placed in an agar gel and the various proteins are separated on the basis of their relative mobilities in an agar gel under the influence of an electric current. The separated proteins are then permitted to diffuse through the agar toward a multispecific antiserum, allowing precipitation and visualization of the separate complexes.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-11827 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 866

[Docket No. 78N-2214]

Medical Devices; Classification of Immunofluorometer Equipment

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying immunofluorometer equipment into class I (general controls). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Srikrishna Vadlamudi, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation.

The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of immunofluorometer equipment:

1. Identification: Immunofluorometer equipment for clinical use with its electrical power supply is a device used to measure the fluorescence of fluorochrome-labeled antigen-antibody complexes. The concentration of these complexes may be measured by means of reflected light. A beam of light is passed through a solution in which a fluorochrome has been selectively attached to serum protein antibody molecules in suspension. The amount of light emitted by the fluorochrome label is detected by a photodetector, which converts light energy into electrical energy. The amount of electrical energy registers on a readout system such as a digital voltmeter or a recording chart. This electrical readout is called the fluorescence value and is used to measure the concentration of antigen-antibody complexes.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that immunofluorometer equipment be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that immunofluorometer equipment be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart E by adding new § 866.4520, to read as follows:

§ 866.4520 Immunofluorometer equipment.

(a) *Identification.* Immunofluorometer equipment for clinical use with its electrical power supply is a device used to measure the fluorescence of fluorochrome-labeled antigen-antibody complexes. The concentration of these complexes may be measured by means of reflected light. A beam of light is passed through a solution in which a fluorochrome has been selectively attached to serum protein antibody molecules in suspension. The amount of light emitted by the fluorochrome label is detected by a photodetector, which converts light energy into electrical energy. The amount of electrical energy registers on a readout system such as a digital voltmeter or a recording chart. This electrical readout is called the fluorescence value and is used to measure the concentration of antigen-antibody complexes.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11828 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2215]

Medical Devices; Classification of Immunonephelometer Equipment

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying immunonephelometer equipment into class I (general controls). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of immunonephelometer equipment:

1. Identification: Immunonephelometer equipment for clinical use with its electrical power supply is a device that measures light scattering from antigen-antibody complexes. The concentration of these complexes may be measured by means of reflected light. A beam of light passed through a solution is scattered by the particles in suspension. The amount of light is detected by a photodetector, which converts light energy into electrical energy. The amount of electrical energy registers on a readout system such as a digital voltmeter or a recording chart. This electrical readout is called the light-scattering value and is used to measure the concentration of antigen-antibody complexes.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that immunonephelometer equipment be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that immunonephelometer equipment be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart E by adding new § 866.4540, to read as follows:

§ 866.4540 Immunonephelometer equipment.

(a) *Identification.* Immunonephelometer equipment for clinical use with its electrical power supply is a device that measures light scattering from antigen-antibody complexes. The concentration of these complexes may be measured by means of reflected light. A beam of light passed through a solution is scattered by the particles in suspension. The amount of light is detected by a photodetector, which converts light energy into electrical energy. The amount of electrical energy registers on a readout system such as a digital voltmeter or a recording chart. This electrical readout is called the light-scattering value and is used to measure the concentration of antigen-antibody complexes.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affiars.

[FR Doc. 80–11829 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2216]

Medical Devices; Classification of Ouchterlony Agar Plates

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying Ouchterlony agar plates into class I (general controls). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of Ouchterlony agar plates:

1. Identification: An Ouchterlony agar plates for clinical use is a device that containing and agar gel used to examine antigen-antibody reactions In immunodiffusion, antibodies and antigens migrate toward each other through gel which originally contained neither of these reagents. As the reagents come in contact with each other, they combine to form a precipitate that is trapped in the gel matrix and is immobilized.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that Ouchterlony agar plates be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. Although care must be taken during manufacture to ensure that the plates are level, the Panel notes that these plates are extremely simple devices that perform satisfactorily during normal use.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that Ouchterlony agar plates be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drug proposes to amend Part 866 in Subpart D by adding new § 866.4600, to read as follows:

§ 866.4600 Ouchterlony agar plate.

(a) *Identification:* An Ouchterlony agar plate for clinical use is a device containing an agar gel used to examine antigen-antibody reactions. In immunodiffusion, antibodies and antigens migrate toward each other through gel which originally contained neither of these reagents. As the reagents come in contact with each other, they combine to form a precipitate that is trapped in the gel matrix and is immobilized.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857 written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11830 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2217]

Medical Devices; Classification of Radial Immunodiffusion Plates

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying radial immunodiffusion plates into class I (general controls). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of radial immunodiffusion plates:

1. Identification: A radial immunodiffusion plate for clinical use is a device that consists of a plastic plate to which agar gel containing antiserum is added. In radial immunodiffusion, antigens migrate through gel which originally contains specific antibodies. As the reagents come in contact with each other, they combine to form a precipitate that is trapped in the gel matrix and immobilized.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempted from premarket notification under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)).

3. Summary of reasons for recommendation: The Panel recommends that radial immunodiffusion plates be classified into class I because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel recommends that radial immunodiffusion plates be exempt from premarket notification under section 510(k) of the act because the Panel believes that premarket notification is not necessary for the protection of the public health.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device. The Panel members note that this is a simple plastic dish.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that radial immunodiffusion plates be classified into class I (general controls). The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

In response to the Panel's recommendation that manufacturers of a radial immunodiffusion plate be exempt from section 510(k) of the act (21 U.S.C. 360), FDA agrees with the Panel and is proposing that the manufacturer of this device be exempt from premarket notification under section 510(k) of the act and Subpart E of Part 807 of the regulations. The agency has determined that it is not necessary for the protection of the public health that FDA receive premarket notification submissions concerning a radial immunodiffusion plate. The agency does not at this time anticipate that premarket approval will be required for this device. The agency believes that the semiannual updating of device listing under section 510(j)(2) will provide FDA with adequate notice concerning new products within this generic type of device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart E by adding new § 866.4800, to read as follows:

§ 866.4800 Radial immunodiffusion plate.

(a) *Identification.* A radial immunodiffusion plate for clinical use is a device that consists of a plastic plate to which agar gel containing antiserum is added. In radial immunodiffusion, antigens migrate through gel which originally contains specific antibodies. As the reagents come in contact with each other, they combine to form a precipitate that is trapped in the gel matrix and immobilized.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in Subpart E of Part 807 of this chapter.

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11831 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2218]

Medical Devices; Classification of Rocket Immunoelectrophoresis Equipment

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying rocket immunoelectrophoresis equipment into class I (general controls). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Srikrishna R. Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757

Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of rocket immunoelectrophoresis equipment:

1. Identification: Rocket immunoelectrophoresis equipment for clinical use is a device used to perform a specific test on proteins by using a procedure called rocket immunoelectrophoresis. In this procedure, an electric current causes the protein in a solution to migrate through agar gel containing specific antisera. The protein precipitates with the antisera in a rocket-shaped pattern, giving the name to the device. The height of the peak (or the area under the peak) is proportional to the concentration of the protein.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that rocket immunoelectrophoresis equipment be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that rocket immunoelectrophoresis equipment be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart E by adding new § 866.4830, to read as follows:

§ 866.4830 Rocket immunoelectrophoresis equipment.

(a) *Identification.* Rocket immunoelectrophoresis equipment for clinical use is a device used to perform a specific test on proteins by using a procedure called rocket immunoelectrophoresis. In this procedure, an electric current causes the protein in solution to migrate through agar gel containing specific antisera. The protein precipitates with the antisera in a rocket-shaped pattern, giving the name to the device. The height of the peak (or the area under the peak) is proportional to the concentration of the protein.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11832 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2219]

Medical Devices; Classification of Support Gels

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying support gels into class I (general controls). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of support gels:

1. Identification: A support gel for clinical use is a device that consists of an agar or agarose preparation that is used while measuring various kinds of, or parts of, protein molecules by various immunochemical techniques, such as immunoelectrophoresis, immunodiffusion, or chromatography.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that support gels be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that support gels be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart E by adding new § 866.4900, to read as follows:

§ 866.4900 Support gel.

(a) *Identification:* A support gel for clinical use is a device that consists of an agar or agarose preparation that is used while measuring various kinds of, or parts of, protein molecules by various

immunochemical techniques, such as immunoelectrophoresis, immunodiffusion, or chromatography.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11833 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2220]

Medical Devices; Classification of Albumin Immunological Test Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying albumin immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of albumin immunological test systems:

1. Identification: An albumin immunological test system is a device that consists of a the reagents used to measure by immunochemical techniques the albumin (a plasma protein) in serum and other body fluids. Measurement of albumin aids in the diagnosis of kidney and intestinal diseases.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the albumin immunological test system be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, stability, precision, sensitivity, and specificity, and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Albumin levels may be reduced in nephrosis (kidney disease), proteinuria (protein in urine), protein-losing enteropathies (diseases of the small bowel), gastroenteropathis (diseases of the stomach and small intestine), rheumatoid arthritis, and viral hepatitis. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, stability, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1 through 5).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of kidney and intestinal diseases. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that albumin immunological test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Earle, D. P., "Abnormal Albumins," *in* "Cecil-Loeb Textbook of Medicine," 12th ed., edited by Beeson, P. B. and W. McDermott, W. B. Saunders Co., Philadelphia, pp. 1194–1195, 1967.

2. Keyser, J. W. and M. Cawson, "A Serum Reference Standard for Automated Total Protein and Albumin Procedures, "*Clinical Chemistry*, 18:335, 1970.

3. Murayama, M., "The Structure of Serum Albumin," *in* "Serum Proteins and the Dysproteinemias," edited by F. W. Sunderman, and F. W. Sunderman, Jr., J. B. Lippincott Co., Philadelphia, pp. 1–4, 1964.

4. Meinke, W. W., Standard Reference Materials for Clinical Measurements, *Analytical Chemistry*, 43:28A–47A, 1971.

5. Peters, T. J., "Serum Albumin" *in* "The Plasma Proteins, Structure, Function and Genetic Control," Vol. 1, 2d Ed., Edited by F. W. Pittman, Academic Press, New York, pp. 133–181, 1975.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 by adding new Subpart F and new § 866.5040, to read as follows:

Subpart F—Immunological Test Systems

§ 866.5040 Albumin immunological test system.

(a) *Identification.* An albumin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the albumin (plasma protein) in serum and other body fluids. Measurement of albumin aids in the diagnosis of kidney and intestinal diseases.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers

Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-11834 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 866

[Docket No. 78N-2221]

Medical Devices; Classification of Prealbumin Immunological Test Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying prealbumin immunological test systems into class I (general controls). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Srikrishna Vadlamudi, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of prealbumin immunological test systems:

1. Identification: A prealbumin immunological test system is a device that consist of the reagents used to measure by immunochemical techniques the prealbumin (a plasma protein) in serum and other body fluids. Measurement of prealbumin levels in serum may aid in the assessment of the patient's nutritional status.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that the prealbumin immunological test system be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that prealbumin immunological test systems be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5060, to read as follows:

§ 866.5060 Prealbumin immunological test system.

(a) *Identification:* A prealbumin immunological test system is a device that consist of the reagents used to measure by immunochemical techniques the prealbumin (a plasma protein) in serum and other body fluids. Measurement of prealbumin levels in serum may aid in the assessment of the patient's nutritional status.

(b) *Classification:* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-11835 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 866

[Docket No. 78N-2222]

Medical Devices; Classification of Human Allotypic Marker Immunological Test Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying human allotypic marker immunological test systems into class I (general controls). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Srikrishna R. Vadlamudi, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the

development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of human allotypic marker immunological test systems:

1. Identification: A human allotypic marker immunological test system is a device that consists of the reagents used to identify by immunochemical techniques the inherited human protein allotypic markers (such as Gm2 and Km allotypes) in serum, saliva, and other biological fluids. The identification may be used while studying population genetics.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that the human allotypic marker immunological test system be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that human allotypic marker immunological test systems be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5065, to read as follows:

§ 866.5065 Human allotypic marker immunological test system.

(a) *Identification.* A human allotypic marker immunological test system is a device that consists of the reagents used to identify by immunochemical techniques the inherited human protein allotypic markers (such as Gm2 and Km allotypes) in serum, saliva, and other biological fluids. The identification may be used while studying population genetics.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11836 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2223]

Medical Devices; Classification of Alpha-1-Antichymotrypsin Immunological Test Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying alpha-1-antichymotrypsin immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of alpha-1-antichymotrypsin immunological test systems:

1. Identification: An alpha-1-antichymotrypsin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques alpha-1-antichymotrypsin (a protein) in serum, tissues, and body fluids. Alpha-1-antichymotrypsin helps protect tissues against proteolytic (protein-splitting) enzymes released during infection.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standards for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the alpha-1-antichymotrypsin immunological test system be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, stability, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Alpha-1-antichymotrypsin is a naturally occurring protein in human serum and semen (Refs. 1, 2, and 3). Alpha-1-antichymotrypsin is one of five known inhibitors of enzymes that break down proteins. The exact function of alpha-1-antichymotryposin is still to be determined. Nevertheless, it is involved in the protection of tissues against proteolytic (protein-splitting) enzymes released during infection (Refs. 4 through 6). The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, stability, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and experience with, the device and upon a review of the literature (Refs. 1 through 6).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of unexplained tissue damage due to infections. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that alpha-1-antichymotrypsin

immunological test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Schelp, F. P., P. Migasena, P. Pongpaew, W. H. P. Schreurs, and V. Supawan, "Serum Proteinase Inhibitors and Other Serum Proteins in Protein-energy Malnutrition," *British Journal of Nutrition*, 38:31–38, 1977.

2. Orjasaeter, H., "Study of Substances Related to Carcinoembryonic Antigens CEA–NCA and Association With Alpha-1-Antichymotrypsin," *Acta Pathologica Microbiology Scandinavia*, Section C, 84:235–244, 1976.

3. Schill, W. B., "Quantitative Determination of High Molecular Weight Serum Proteinase Inhibitors in Human Semen," *Andrologia* 8(4):359–364, 1976.

4. Heimburger, N., H. Haupt, and H. G. Schwick, "Proteinase Inhibitors of Human Plasma," Proceedings of the International Research Conference on Proteinase Inhibitors, Edited by Futz, H., H. Tschesche, and Walter de Gryter, Munich, November 4 through 6, 1970, Berlin, New York, 1971.

5. Kosaka, S. and M. Tazawa "Alpha-1-Antichymotrypsin in Rheumatoid Arthritis," *Tohoku Journal of Experimental Medicine*, 119:369–375, 1976.

6. Ohlsson, K. and U. Akesson, "Alpha-1-Antichymotrypsin Interaction With Cationic Proteins from Granulocytes," *Clinica Chimica Acta* 73:285–291, 1976.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5080, to read as follows:

§ 866.5080 Alpha-1-antichymotrypsin immunological test system.

(a) *Identification.* An alpha-1-antichymotrypsin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques alpha-1-antichymotrypsin (a protein) in serum, tissues, and body fluids. Alpha-1-antichymotrypsin helps protect tissues against proteolytic (protein-splitting) enzymes released during infection.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11837 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2224]

Medical Devices; Classification of Antimitochondrial Antibody Immunological Test Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying antimitochondrial antibody immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of antimitochondrial antibody immunological test systems:

1. Identification: An antimitochondrial antibody immunological test system is a device that consists of the reagents used to measure by immunochemical techniques antimitochondrial antibodies in human serum. The measurements aid in the diagnosis of diseases that produce a spectrum of autoantibodies (antibodies produced against the body's own tissue), such as primary biliary cirrhosis (degeneration of liver tissue) and chronic active hepatitis (inflammation of the liver).

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that the antimitochondrial antibody immunological test system be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, stability, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. These tests are useful in the evaluation of patients in whom primary biliary cirrhosis, chronic active hepatitis, and other diseases produce a spectrum of autoantibodies. These antibodies are multi-specific and will react with components of cells from many species. Antimitochondrial antibodies may belong to any of the immunoglobulin classes IgM, IgG, or IgA. Immunological test procedures that are used to detect antimitochondrial antibodies include complement fixation, passive agglutination, radioimmunoassay, and immunofluorescence assay. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, stability, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical

experience with, the device and upon a review of the literature (Refs. 1 through 6).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of primary biliary cirrhosis, chronic active hepatitis, and other diseases producing a spectrum of autoantibodies. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that antimitochondrial antibody immunological test systems be classified into class II (performance standards). The agency believes that a performance standard is necesary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Aho, K., I. Rostedt, and N. E. Saris, "Reactivity of Various Anticardiolipin Antibodies With Intact Mitochondria," *Clinical and Experimental Immunology*, 14(4):573–579, 1973.

2. Candeias, J. A. N., F. Antonacio, H. Sette, and L. C. da Silva, "Occurrence of Hepatitis-Assoicated Antigen (HAA) Subdeterminates ad and ay in Blood Donors, Acute and Chronic Liver Disease," *Review Institute Medicine Tropical*, Sao Paulo, Brazil, 16(4):226–231, 1974.

3. Glynn, L. E., "Immunopathology of Liver Disease," *Progress in Liver Diseases*, 5:311–325, 1976.

4. Hilton, A. M., B. E. Boues, P. J. Smith, J. Sharpe, and I. W. Dymock, "Liver Disease in Patients with Joint Symptoms," *Annals of Rheumatic Diseases*, 33(6):540–547, 1974.

5. Sherlock, S. "Primary Biliary Cirrhosis," *Progress in Liver Diseases*, 5:559–574, 1976.

6. Steigmann, F., D. Dourdourekas, N. Shobassay, S. B. V. Vittal, P. B. Szanto, U. Khin, H. Ainis, M. Telischi, "Humoral Response in Patients With Liver Disease," *American Journal of Gastroenterology*, 61(5):349–355, 1974.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5090, to read as follows:

§ 866.5090 Antimitochondrial antibody immunological test system.

(a) *Identification.* An antimitochondrial antibody immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the antimitochondrial antibodies in human serum. The measurements aid in the diagnosis of diseases that produce a spectrum of autoantibodies (antibodies produced against the body's own tissue), such as primary billiary cirrhosis (degeneration of liver tissue) and chronic active hepatitis (inflammation of the liver).

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11838 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2225]

Medical Devices; Classification of Antinuclear Antibody Immunological Test Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying antinuclear antibody immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of antinuclear antibody immunological test systems:

1. Identification: An antinuclear antibody immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the autoimmune antibodies in serum and tissues that react with cellular nuclear constituents (molecules present in the nucleus of a cell, such as ribonucleic acid, deoxyribonucleic acid, or nuclear proteins) in serum or body fluids. The measurements aid in the diagnosis of systemic lupus erythematosus, a multisystem autoimmune disease (a disease in which antibodies attack the victim's own tissues), hepatitis (a liver disease), rheumatoid arthritis, Sjogren's syndrome (arthritis with inflammation of the eye, eyelid, and salivary glands), and systemic sclerosis (chronic hardening and shrinking of many body tissues).

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that the antinuclear antibody immunological test system be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, stability, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. This test is useful in diagnosing systemic lupus erythematosus. Absence of systemic lupus

erythematosus antinuclear antibody may exclude diagnosing this condition. However, a positive test result has been associated with a large number of disorders, such as rheumatoid arthritis and Sjogren's syndrome. It should be noted that the antinuclear antibody may be positive in normal individuals (Refs. 1 through 3). Latex test procedures have been shown to be less sensitive than indirect immunofluorescent methods (Ref. 4). A variety of nuclear antigens react with systemic lupus erythematosus sera, such as DNA (deoxyribonucleic acid) both native and denatured, and nucleoproteins (proteins associated with DNA) such as histones (small alkaline proteins). The use of immunofluorescent (antibodies chemically combined with fluorescent dye) methods has led to recognition of a variety of patterns of fluorescent staining of the nucleus that have diagnostic significance. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, stability, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1 through 4).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of autoimmune diseases. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that antinuclear antibody immunological test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Casals, S. P., G. J. Friou, and P. O. Teague, "Specific Nuclear Reaction Pattern of Antibody to DNA in Lupus Erythematosus Sera," *Journal of Laboratory and Clinical Medicine,* 62: 625–631, 1963.

2. Gonzalez, E. N. and N. F. Rothfield, "Immunoglobulin Class and Pattern of Nuclear Fluorescence in Systemic Lupus Erythematosus," *New England Journal of Medicine,* 274: 1333–1338, 1966.

3. Rothfield, N. F. and B. D. Stollar, "The Relation of Immunoglobulin Class, Pattern of Anti-Nuclear Antibody, and Complement-Fixing Antibodies to DNA in Sera from Patients with Systemic Lupus Erythematosus," *Journal of Clinical Investigation,* 46:1785–1794, 1967.

4. Chapman, J. C., "Lupus Erythematosus Latex Tests Compared with the Immunofluorescence Method for Antinuclear Factor," *American Journal of Medical Technology,* 42(5): 126–129, 1976.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5100, to read as follows:

§ 866.5100 Antinuclear antibody immunological test system.

(a) *Identification:* An antinuclear antibody immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the autoimmune antibodies in serum and tissues that react with cellular nuclear constituents (molecules present in the nucleus of a cell, such as ribonucleic acid, deoxyribonucleic acid, or nuclear proteins) in serum or body fluids. The measurements aid in the diagnosis of systemic lupus erythematosus, a multisystem autoimmune disease (a disease in which antibodies attack the victim's own tissues), hepatitis (a liver disease), rheumatoid arthritis, Sjogren's syndrome (arthritis with inflammation of the eye, eyelid, and salivary glands), and systemic sclerosis (chronic hardening and shrinking of many body tissues).

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11839 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2226]

Medical Devices; Classification of Antiparietal Antibody Immunological Test Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying antiparietal antibody immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910. 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of antiparietal antibody immunological test systems:

1. Identification: An antiparietal antibody immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the specific antibody for gastric parietal cells in human serum and body fluids. Gastric parietal cells are those cells located in the stomach that produce a protein that enables vitamin B12 to be absorbed by the body. The measurements aid in the diagnosis of vitamin B12 deficiency (or pernicious anemia), atrophic gastritis (inflammation of the stomach), and autoimmune connective tissue diseases (diseases resulting when the body produces antibodies against its own tissues).

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the antiparietal antibody immunological test system be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, stability, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The antiparietal antibody immunological test system measurements aid in the diagnosis of pernicious anemia (malabsorption of vitamin B12), atrophic gastritis (inflammation of the stomach) and autoimmune connective tissue diseases (diseases resulting when the body produces antibodies that attack its own tissues). Immunofluorescent (using antibodies chemically combined with fluorescent dye) assay is the method chosen by most clinical laboratories for measuring antiparietal antibodies. Parietal cell antibodies are present in 90 percent of patients with pernicious anemia, and to a lesser degree in patients with such other conditions as thyroiditis (inflammation of thyroid gland), Sjogren's syndrome (inflammation of the eye), atrophic gastritis, and gastric ulcer. Parietal cell antibodies also occur in a low percentage of normal persons. Levels increase with advancing age, and elevated levels are more common in women. For these reasons, additional tests are usually needed to interpret the significance of antiparietal antibody levels. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, stability, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1 through 4).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of pernicious anemia and atrophic gastritis. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that antiparietal antibody immunological test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by this device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Bigazzi, P. E. and N. R. Rose, "Tests for Antibodies to Tissues Specific Antigens," *in* "Manual of Clinical Immunology," Edited by Noel R. Rose and Herman Friedman, published by the American Society for Microbiology, Washington, DC, pp. 682–691. 1976.

2. Goldberg, L. S. and H. H. Fudenberg, "The Autoimmune Aspects of Pernicious Anemia," *American Journal of Medicine*, 46:489–494, 1969.

3. Bernhadt, H. L. L. Burkett, M. L. Fields, and J. Killian, "The Diagnostic Significance of the Parietal Cell Immunofluorescent Test," *Annals of Internal Medicine*, 63:635–641, 1965.

4. Strickland, R. G., S. Baurn, L. A. E. Ashworth, and K. B. Taylor, "A Correlative Study of Immunological Phenomenon in Pernicious Anemia," *Clinical and Experimental Immunology*, 8:25–36, 1971.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5110, to read as follows:

§ 866.5110 Antiparietal antibody immunological test system.

(a) *Identification.* An antiparietal antibody immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the specific antibody for gastric parietal cells in human serum and body fluids. Gastric parietal cells are those cells located in the stomach that produce a protein that enables vitamin B_{12} to be absorbed by the body. The measurements aid in the diagnosis of vitamin B_{12} deficiency (or pernicious anemia), atrophic gastritis (inflammation of the stomach), and autoimmune connective tissue diseases (diseases resulting when the body produces antibodies against its own tissues).

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11840 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2227]

Medical Devices; Classification of Antismooth Muscle Antibody Immunological Test Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying antismooth muscle antibody immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of antismooth muscle antibody immunological test systems:

1. Identification: An antismooth muscle antibody immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the antismooth muscle antibodies (antibodies to nonstriated, involuntary muscle) in serum. The measurements aid in the diagnosis of chronic hepatitis (inflammation of the liver) and autoimmune connective tissue diseases (diseases resulting from antibodies produced against the body's own tissues).

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that the antismooth muscle antibody immunological test system be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, stability, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The measurements aid in the diagnosis of chronic hepatitis and autoimmune connective tissue diseases that produce a spectrum of autoantibodies against a variety of antigens (Refs. 1 through 4).The antibodies belong mainly to the IgG class of immunoglobulins, but can also be found in the IgM (high molecular weight immunoglobulin) class. Methods that have been used to detect antismooth muscle antibodies include complement fixation, passive hemagglutination, gel diffusion, counter immunoelectrophoresis, radioimmunoassay, and immunofluorescent assay. Significant numbers of apparently normal individuals will also demonstrate antismooth muscle antibody. Consequently, for the definite diagnosis of a given disorder, additional, more specific tests are needed to interpret the significance of the test results. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, stability, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of the data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1 through 4).

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of chronic hepatitis and primary biliary cirrhosis (liver diseases). Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that antismooth muscle antibody immunological test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The agency believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the Office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Doniach, D., I. M. Roitt, J. G. Walker, and S. Sherlock, "Tissue Antibodies in Primary Biliary Cirrhosis, Active Chronic (Lupoid) Hepatitis, Cryptogenic Cirrhosis, and other Liver Diseases and Their Clinical Implications," *Clinical and Experimental Immunology*, 1:237–262, 1966.

2. Johnson, G. D., E. J. Holborow, and L. E. Glynn, "Antibody to Smooth Muscle In Patients with Liver Disease," *Lancet*, 2:878–879, 1965.

3. Whitehouse, J. M. A. and E. J. Holborow, "Smooth Muscle Antibody in Malignant Disease," *British Medical Journal*, 4:511–513, 1971.

4. Whittingham, S., J. Irwin, I. R. McKay, and M. Smalley, "Smooth Muscle Autoantibody in "Autoimmune" Hepatitis," *Gastroenterology*, 51:499–505, 1966.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5120, to read as follows:

§ 866.5120 Antismooth muscle antibody immunological test system.

(a) *Identification.* An antismooth muscle antibody immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the antismooth muscle antibodies (antibodies to nonstriated, involuntary muscle) in serum. The measurements aid in the diagnosis of chronic hepatitis (inflammation of the liver) and autoimmune connective tissue diseases (diseases resulting from antibodies produced against the body's own tissues).

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11841 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2228]

Medical Devices; Classification of Alpha-1-Antitrypsin Immunological Test Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying alpha-1-antitrypsin immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device.

After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 30910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of alpha-1-antitrypsin immunological test systems:

1. Identification: An alpha-1-antitrypsin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the alpha-1-antitrypsin (a plasma protein) in serum, tissue, and other body fluids. The measurements aid in the diagnosis of several conditions including juvenile and adult cirrhosis of the liver. In addition, alpha-1-antitrypsin deficiency has been associated with pulmonary emphysema.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Reasons for recommendation: The Panel recommends that the alpha-1-antitrypsin immunological test system be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, stability, precision, sensitivity, and specificity thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Alpha-1-antitrypsin (AAT) deficiency has been associated with pulmonary emphysema and cirrhosis of the liver in infants and adults. Serum deficiency of AAT is noted in the following diseases: chronic obstructive disease (an asthma-like condition) in adults, juvenile and adult cirrhosis of the liver, neonatal hepatitis (inflammation of the liver in the very young), and hepatocellular carcinoma (cancer of the liver) (Refs. 1 through 4). AAT levels have been reported to be increased in lung cancer. Further studies are required to determine if the serum level is a reflection of tumor growth in patients with cancer (Refs. 1 and 3). The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, stability, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1 through 4).

5. Risks to health: Misdiagnosis and inappropriate therapy. Failure of the device to perform satisfactorily may lead to an error in the diagnosis of alpha-1-antitrypsin deficiency and associated disorders, such as pulmonary emphysema (enlargement of small air spaces of the lung) and cirrhosis (degeneration of the liver). Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that alpha-1-antitrypsin immunological test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk and may be seen by interested persons from 9 a.m. to 4 p.m., Monday through Friday.

1. Harris, C. C., A. Primacke, and M. H. Cohen, "Elevated Alpha-1-Antitrypsin Serum Levels in Lung Cancer Patients," *Cancer* 34:280–281, 1974.

2. Falk, G. A. and J. P. Smith, "Chronic Bronchitis: A Seldom Noted Manifestation of Homozygous Alpha–1–Antitrypsin Deficiency," *Chest*, 60: 166–169, 1971.

3. Tuttle, W. C., and R. K. Jones "Fluorescent Antibody Studies of Alpha–1–Antitrypsin in Adult Human Lung," *American Journal of Clinical Pathology*, 64:477–482, 1975.

4. Lieberman, J., R. M. Silton, C. M. Agliozzo and J. McMahon, "Hepatocellular Carcinoma and Intermediate Alpha–1–Antitrypsin Deficiency (MZ Phenotype)," *American Journal of Clinical Pathology*, 64:304–310, 1975.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs, proposes to amend Part 866 in Subpart F by adding new § 866.5130, to read as follows:

§ 866.5130 Alpha–1–antitrypsin immunological test system.

(a) *Identification.* An alpha–1–antitrypsin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the alpha–1–antitrypsin (a plasma protein) in serum, tissue, and other body fluids. The measurements aid in the diagnosis of several conditions including juvenile and adult cirrhosis of the liver. In addition, alpha–1–antitrypsin deficiency has been associated with pulmonary emphysema.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regading this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11842 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2229]

Medical Devices; Classification of Bence-Jones Proteins Immunological Test Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying Bence-Jones proteins immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class II. The effect of classifying a device into

class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of Bence-Jones proteins immunological test systems:

1. Identification: A Bence-Jones proteins immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the Bence-Jones proteins in urine and serum. Immunoglobulin molecules normally consist of pairs of polypeptide chains (subunits) of unequal size (light chains and heavy chains) bound together by several disulfide bridges. In some cancerous conditions, there is a proliferation of one plasma cell (antibody-producing cell) with excess production of light chains of one specific kind (monoclonal light chains). These free homogeneous light chains not associated with an immunoglobulin molecule can be found in a patient's plasma and urine, and have been called Bence-Jones proteins. Measurement of Bence-Jones proteins and determination that they are monoclonal aid in the diagnosis of multiple myeloma (malignant proliferation of plasma cells), Waldenstrom's macroglobulinemia (increased production of large immunoglobulins by spleem and bone marrow cells), leukemia (cancer of the blood-forming organs), and lymphoma (cancer of the lymphoid tissue).

2. Recommended Classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that the Bence-Jones proteins immunological test system be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, stability, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Bence-Jones proteins are monoclonal light chain proteins. They are made and secreted by plasma cells in association with malignant immunoproliferative disorders (cancer of the antibody-producing tissue cells). They are circulated in plasma, are broken down by the kidney, and are excreted in the urine. Although Bence-Jones proteins are found most often in patients with multiple myeloma, they may be present in a variety of disorders, such as Waldenstrom's macroglobulinemia and lymphocytic neoplasms (lymphomas and leukemia). Bence-Jones proteins are readily detected by immunochemical methods (immunoelectrophoresis and immunodiffusion) in both serum and urine specimens.

The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, stability, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1 through 4).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of multiple myeloma or other lymphoproliferative disorders. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that Bence-Jones proteins immunological test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Deegan, M. J., "Bence-Jones Proteins: Nature, Metabolism, Detection, and Significance," *Annals of Clinical and Laboratory Science* 6(1):38–46, 1976.

2. Perry, M. C. and R. A. Kyle, "The Clinical Significance of Bence-Jones Proteinuria," *Mayo Clinic Proceedings* 50(5):234–238, 1975.

3. Solomon, A., "Bence-Jones Proteins and Light Chains of Immunoglobulins," *New England Journal of Medicine*, 294(1):17–23, 1976.

4. Solomon, A. "Bence-Jones Proteins and Light Chains of Immunoglobulins," *New England Journal of Medicine*, 294(2):91–98, 1976.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5150, to read as follows:

§ 866.5150 Bence-Jones proteins immunological test system.

(a) *Identification.* A Bence-Jones proteins immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the Bence-Jones proteins in urine and serum. Immunoglobulin molecules normally consist of pairs of polypeptide chains (subunits) of unequal size (light chains and heavy chains) bound together by several disulfide bridges. In some cancerous conditions, there is a proliferation of one plasma cell (antibody-producing cell) with excess production of light chains of one specific kind (monoclonal light chains). These free homogeneous light chains not associated with an immunoglobulin molecule can be found in a patient's plasma and urine, and have been called Bence-Jones proteins. Measurement of Bence-Jones proteins and determination that they are monoclonal aid in the diagnosis of multiple myeloma (malignant proliferation of plasma cells), Waldenstrom's macroglobulinemia (increased production of large immunoglobulins by spleen and bone marrow cells), leukemia (cancer of the blood-forming organs), and lymphoma (cancer of the lymphoid tissue).

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be

identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-11843 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 866

[Docket No. 78N-2284]

Medical Devices; Classification of Beta Globulin Immunological Test Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying beta globulin immunological test systems into class I (general controls). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Srikrishna Vadlamudi, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of beta globulin immunological test systems:

1. Identification: A beta globulin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques beta globulins (serum protein) in serum and other body fluids. Beta globulin proteins include beta lipoprotein, transferrin, glycoproteins, and complement and are rarely associated with specific pathological disorders..

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that the beta globulin immunological test system be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that beta globulin immunological test systems be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5160, to read as follows:

§ 866.5160 Beta globulin immunological test system.

(a) *Identification.* A beta globulin immunological test system is a device that consists of reagents used to measure by immunochemical techniques beta globulins (serum protein) in serum and other body fluids. Beta globulin proteins include beta lipoprotein, transferrin, glycoproteins, and complement and are rarely associated with specific pathologic disorders.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-11844 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 866

[Docket No. 78N-2230]

Medical Devices; Classification of Breast Milk Immunological Test Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying breast milk immunological test systems into class I (general controls). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Srikrishna Vadlamudi, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, and FDA advisory committee, made the following recommendation

regarding the classification of breast milk immunological test systems:

1. Identification: A breast milk immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the breast milk proteins.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that the breast milk immunological test system be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that breast milk immunological test systems be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficent to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5170, to read as follows:

§ 866.5170 Breast milk immunological test system.

(a) *Identification.* A breast milk immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the breast milk proteins.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 11845 Filed 4–21–80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 866

[Docket No. 78N–2231]

Medical Devices; Classification of Carbonic Anhydrase B and C Immunological Test Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying carbonic anhydrase B and C immunological test systesm into class I (general controls). FDA is also publishing the recomendation of the Immunology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of carbonic anhydrase B and C immunological test systems:

1. Identification: A carbonic anhydrase B and C immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the specific carbonic anhydrase protein molecules in human serum and other body fluids. Measurements of carbonic anhydrase B and C aid in the diagnosis of abnormal hemoglobin metabolism.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that the carbonic anhydrase B and C immunological test system be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that carbonic anhydrase B and C immunological test systems be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5200, to read as follows:

§ 866.5200 Carbonic anhydrase B and C immunological test system.

(a) *Identification.* A carbonic anhydrase B and C immunological test system is a device that consists of the reagents used to measure by immunochemical techniques specific carbonic anhydrase protein molecules in human serum and other body fluids. Measurements of carbonic anhydrase B and C aid in the diagnosis of abnormal hemoglobin metabolism.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments

may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs

[FR Doc. 80-11846 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 866

[Docket No. 78N-2232]

Medical Devices; Classification of Ceruloplasmin Immunological Test Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying ceruloplasmin immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Srikrishna Vadlamudi, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of ceruloplasmin immunological test systems:

1. Identification: A ceruloplasmin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the ceruloplasmin (copper-transporting serum protein) in serum, body fluids, or tissues. Measurements of ceruloplasmin aid in the diagnosis of copper metabolism disorders.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that the ceruloplasmin immunological test system be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, stability, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. A decrease in serum ceruloplasmin to less than 20 milligrams per deciliter is almost always observed in Wilson's disease, a genetic disease characterized by toxi deposits of copper in the tissues (Ref. 1). Accumulations of copper may affect brain function, or the liver may be exclusively involved. When the brain is involved, central nervous system dysfunction such as tremor and incoordination may occur. In the hepatic (liver) form of the disease, neurologic signs are often minor or absent. Diagnosis of asymptomatic patients is possible, and preventive therapy is effective in delaying and perhaps preventing the appearance of symptoms. Occasionally, asymptomatic patients exhibit normal ceruloplasmin concentrations, and this may introduce diagnostic difficulty. A recent Center for Disease Control (CDC) proficiency survey (Ref. 2) has shown that commercially available antisera gave variable immunological test results. For this reason, CDC recommended the standardization of reagents for these tests. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, stability, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of the data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1 and 2).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of Wilson's disease. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that ceruloplasmin immunological test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The agency believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Sternleib, I., "Present Status of Diagnosis and Prophylaxis of Asymptomatic Patients with Wilson's disease," *in* "Diseases of the Liver and the Biliary Tract," Edited by C. M. Levy, Karger, Basel, Switzerland, pp. 137-142, 1976.

2. Center for Disease Control, "Proficiency Testing Summary Analysis," *in* "Diagnostic Immunology," U.S. Department of Health, Education, and Welfare, Public Health Service, Atlanta, GA, April 1978.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5210, to read as follows:

§ 866.5210 Ceruloplasmin immunological test system.

(a) *Identification.* A ceruloplasmin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the ceruloplasmin (copper-transporting serum protein) in serum, body fluids, or tissues. Measurements of ceruloplasmin aid in the diagnosis of copper metabolism disorders.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-11847 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 866

[Docket No. 78N-2233]

Medical Devices; Classification of Cohn Fraction II Immunological Test Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying Cohn fraction II immunological test systems into class I (general controls). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Srikrishna Vadlamudi, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of Cohn fraction II immunological test systems.

1. Identification: A Cohn fraction II immunological test system is a device that consists of reagents that contain or are used to measure that fraction of plasma containing protein gamma globulins, predominately of the IgG class. The device may be used as a coprecipitant in radioimmunoassay methods, as raw material for the purification of IgG subclasses, and to reduce nonspecific adsorption of plasma proteins in immunoassay techniques. Measurement of these proteins aids in the diagnosis of any disease concerned with abnormal levels of IgG gamma globulins such as agammaglobulinemia or multiple myeloma.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that the Cohn fraction II immunological test system be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that Cohn fraction II immunological test systems be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5220, to read as follows:

§ 866.5220 Cohn fraction II immunological test system.

(a) *Identification.* A Cohn fraction II immunological test system is a device that consists of the reagents that contain or are used to measure that fraction of plasma containing protein gamma globulins, predominately of the IgG class. The device may be used as a coprecipitant in radioimmunoassay methods, as raw material for the purification of IgG subclasses, and to reduce nonspecific adsorption of plasma proteins in immunoassay techniques. Measurement of these proteins aids in the diagnosis of any disease concerned with abnormal levels of IgG gamma globulins such as agammaglobulinemia or multiple myeloma.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-11848 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 866

[Docket No. 78N-2234]

Medical Devices; Classification of Colostrum Immunological Test Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying colostrim immunological test systems into class I (general controls). FDA is also publishing the recommendation of the immunology device classification panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the medical device amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Srikrishna Vadlamudi, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health, Eduction, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of

the Federal Register provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of colostrum immunological test systems:

1. Identification: A colostrum immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the specific proteins in colostrum. Colostrum is a substance excreted by the mammary glands during pregnancy and until production of breast milk begins 1 to 5 days after childbirth.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that the colostrum immunological test system be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that colostrum immunological test systems be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5230, to read as follows:

§ 866.5230 Colostrum immunological test system.

(a) *Identification.* A colostrum immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the specific proteins in colostrum. Colostrum is a substance excreted by the mammary glands during pregnancy and until production of breast milk begins 1 to 5 days after childbirth.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11849 Filed 4–21–80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 866

[Docket No. 78N–2235]

Medical Devices; Classification of Complement Components Immunological Test Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying complement components immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of complement components immunological test systems:

1. Identification: A complement components immunological test system is a device that consists of the reagents used to measure by immunochemical techniques complement components Clq, Clr, Cls, C2, C3, C4, C5, C6, C7, C8, and C9 in serum, biological fluids, and tissues. Complement is a group of serum proteins which destroy infectious agents. Measurement of these proteins aid in the diagnosis of immunologic disorders, especially deficiencies of complement components.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the complement components immunological test system be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, stability, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate thereapy that places the patient at risk unnecessarily. The literature emphasizes the importance of detecting complement component deficiencies (Refs. 2 through 6). Collection and storage of serum samples for functional serological testing with antigen-antibody complexes and immunochemical (electrophoretic) complement assays present special problems because of lability of some complement components (Ref. 1). A variety of complement deficiencies may be transmitted as hereditary defects (Refs. 2 through 6). Deficiencies of C1, C2, and C4 are associated mainly with diseases resembling systemic lupus erythematosus (SLE), a multisystem autoimmune disease (a condition in which antibodies formed against the body's own tissues react with and injure these tissues), and other connective tissue disorders. In addition, patients may have increased susceptibility to infection. Some patients may not be clinically affected. Complement component C3 deficiency has been associated with markedly increased susceptibility to infection with encapsulated bacteria. Complement mediated functions such as hemolytic activity (destruction of red cells), opsonization (coating of infectious agents with antibody), and bactericidal activities are also reduced. Deficiencies of complement components C5, C6, C7, C8, and C9 may also be associated with increased suceptibility to infections in which bacterial lysis (disruption of the bacterial cells) is important in the elimination of the organism.

The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, stability, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1 through 6).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of diseases resembling systemic lupus erythematosus (SLE). Additionally, complement mediated functions may be reduced leading to increased susceptibility to infections. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that complement components immunological test systems be classified into Class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Stites, D. P., "Laboratory Methods for Detection of Antigens and Antibodies," *in* "Basic and Clinical Immunology," Edited by Fudenberg, H. H., D. P. Stities, J. L. Caldwell, and J. V. Wells, Lange Medical Publications, Los Altos, CA, p. 311, 1976.

2. Alper, C. A. and F. S. Rosen, "Genetics of the Complement System," *in* "Advances in Human Genetics," Edited by Harris, H. and K. Hirschhorn, Plenum Press, New York, 7: 141–188, 1976.

3. Kehoe, J. M., "Complement Function and Disorders," *Pediatric Annals,* 5(6):397–404, 1976.

4. Ruddy, S., I. Gigli, and K. F. Austen, "The Complement System of Man," *New England Journal of Medicine,* 287:489–495, 545–549, 592–596, 642–646, 1972.

5. Jersild, C. P. Rubinstein and N. K. Day, "The HLA System and Inherited Deficiencies of the Complement System," *Transplant Review,* 32:43–71, 1976.

6. Alper, C. A. and F. S. Rosen, "Genetic Aspects of the Complement System," *Advances in Immunology,* 14:251–290, 1976.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5240, to read as follows:

§ 866.5240 Complement components immunological test system.

(a) *Identification.* A complement components immunological test system is a device that consists of the reagents used to measure by immunochemical techniques complement components C1q, C1r, C1s, C2, C3, C4, C5, C6, C7, C18, and C9 in serum, biological fluids, and tissues. Complement is a group of serum proteins which destroy infectious agents. Measurement of these proteins data in the diagnosis of immunologic disorders, especially those associated with deficiencies of complement components.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11850 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2236]

Medical Devices; Classification of Complement C_1 Inhibitor (Inactivator) Immunological Test Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying complement C_1 inhibitor (inactivator) immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to ensure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of complement C_1 inhibitor (inactivator) immunological test systems:

1. Identification: A complement C_1 inhibitor (inactivator) immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the complement C_1 inhibitor (a plasma protein) in serum. Complement C_1 inhibitor occurs normally in plasma and blocks the action of the C_1 component of complement (a group of serum proteins which destroy infectious agents). Measurement of complement C_1 inhibitor aids in the diagnosis of hereditary angioneurotic edema (increased blood vessel permeability causing swelling of tissues) and a rare form of angioedema associated with lymphoma (lymph node cancer).

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that the complement C_1 inhibitor (inactivator) immunological test system be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, stability, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may

generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, stability, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of the data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1 through 4).

5. Risks to Health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of hereditary angioneurotic edema. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that complement C_1 inhibitor (inactivator) immunological test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Alper, C. A. and F. S. Rosen, "Genetics of the Complement System" *in* "Advances in Human Genetics," Editors: H. Harris and K. Hirschorn, Plenum Press, NY, pp. 141–188, 1976.

2. Ruddy, S., I. Gigli, and K. F. Austen, "The Complement System of Man," *New England Journal of Medicine*, 287:489–495, 545–549, 592–596, 642–646, 1972.

3. Donaldson, V. H. and F. S. Rosen, "Hereditary Angioneurotic Edema, A Clinical Survey," *Pediatrics*, 37:1017–1027, 1966.

4. Donaldson, V. H. and R. R. Evans, "A Biochemical Abnormality in Hereditary Angioneurotic Edema: Absence of Serum Inhibitor of C_1-Esterase," *American Journal of Medicine*, 35:37–44, 1963.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5250, to read as follows:

§ 866.5250 Complement C_1 Inhibitor (Inactivator) Immunological Test System.

(a) *Identification.* A complement C_1 inhibitor (inactivator) immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the complement C_1 inhibitor (a plasma protein) in serum. Complement C_1 inhibitor occurs normally in plasma and blocks the action of the C_1 component of complement (a group of serum proteins which destroy infectious agents). Measurement of complement C_1 inhibitor aids in the diagnosis of hereditary angioneurotic edema (increased blood vessel permeability causing swelling of tissues) and a rare form of angioedema associated with lymphoma (lymph node cancer).

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Asssociate Commissioner for Regulatory Affairs.

[FR Doc. 80–11851 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2237]

Medical Devices; Classification of Complement C_{3b} Inactivator Immunological Test Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying complement C_{3b} inactivator immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments. FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of complement C_{3b} inactivator immunological test systems:

1. Identification: A complement C_{3b} inactivator immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the complement C_{3b} inactivator (a plasma protein) in serum. Complement is a group of serum proteins that destroy infectious agents. Measurement of complement C_{3b} inactivator aids in the diagnosis of inherited antibody dysfunction.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that the complement C_{3b} inactivator immunological test system be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, stability, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecesarily. Complement C_{3b} inactivator

blocks the activity of C_{3b}, an inhibitor of the alternative pathway of the classic system of activation of complement. A single patient with inherited C_{3b} inactivator deficiency has been described (Ref. 2). The patient's serum is deficient in complement-mediated functions, such as hemolytic activity against sensitized sheep red cells, and antibody resistance to infectious disease. As a result, the patient has had a continuous history of life-threatening bacterial infections. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, stability, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1, 2, and 3).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of complement C_{3b} inactivator deficiency. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that complement C_{3b} inactivator immunological test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Kehoe, J. M., "Complement Function and Disorders," *Pediatric Annals,* 5(6):397–404, 1976.

2. Alper, C. A. and F. S. Rosen, "Genetics of the Complement System" *in* "Advances in Human Genetics," Edited by Harris, H. and K. Hirschhorn, Plenum Press, New York, pp. 141–188, 1976.

3. Agnello, V., "Complement Deficiency States," *Medicine* (Baltimore), 57(1):1–23, 1978.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5260, to read as follows:

§ 866.5260 Complement C_{3b} inactivator immunological test system.

(1) *Identification:* A complement C_{3b} inactivator immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the complement C_{3b} inactivator (a plasma protein) in serum. Complement is a group of serum proteins that destroy infectious agents. Measurement of complement C_{3b} inactivator aids in the diagnosis of inherited antibody dysfunction.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11852 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2238]

Medical Devices; Classification of C-Reactive Protein Immunological Test Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying C-reactive protein immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of C-reactive protein immunological test systems:

1. Identification: A C-reactive protein immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the C-reactive protein in serum, plasma, and body fluids. Measurements of C-reactive protein aids in evaluation of the amount of injury to body tissues.

2. Recommended classification: Class II (performance standards). The Panel recommends that the C-reactive protein immunological test system be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, stability, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. C-reactive protein is not an antibody, but elevated levels appear nonspecifically in a wide variety of inflammatory, necrotic (tissue-destructive), and infective conditions. It is an important index to general tissue injury. It is also noted in moderate-to-advanced carcinoma (cancer) where tissue wastage has occurred. C-reactive protein determination aids in the evaluation of acute infection and tissue damage from conditions such as tuberculosis, rheumatic fever, and coronary occlusion. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, stability, and specificity. The Panel believes

that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel member's personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1 through 3).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of a variety of inflammatory, necrotic, and infective conditions. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that C-reactive protein immunoligical test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Carnevali, G. and E. Delprete, "Comparative Evaluation Between the Precipitation Test, Latex Test, and the Radial Immunodiffusion Test for Determination of C-reactive Protein." *Quaderni Sclavo di Diagnostica Clinical Medicine*, 87(1):120–128, 1976.

2. Claus, D. R., A. P. Osmand and H. Gewurz, "Radioimmunoassay of Human C-Reactive Protein and Levels in Normal Sera," *Journal of Laboratory and Clinical Medicine*, 87(1):120–128, 1976.

3. Nilsson, L., "Comparative Testing of Precipitation Methods for Quantitation of C-Reactive Protein in Blood Serum," *Acta Pathologica Microbiologica Scandinavica*, 73:129–144, 1968.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5270, to read as follows:

§ 866.5270 C-reactive protein immunological test system.

(a) *Identification.* A C-reactive protein immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the C-reactive protein in serum, plasma, and body fluids. Measurements of C-reactive protein aids in evaluation of the amount of injury to body tissues.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11853 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2239]

Medical Devices; Classification of Properdin Factor B Immunological Test Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying properdin factor B immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of properdin factor B immunological test systems:

1. Identification: A properdin factor B immunological test system is a device that consists of the reagents used to measure by immunochemical techniques properdin factor B in serum and body fluids. The deposition of properdin factor B in body tissues or a corresponding depression in the amount of properdin factor B in serum and body fluids is evidence of the involvement of the alternative to the classical pathway of activation of complement (a group of plasma proteins which cause the destruction of cells which are foreign to the body). Measurement of properdin factor B aids in the diagnosis of several kidney diseases, e.g., chronic glomerulonephritis (inflammation of the glomeruli of the kidney), lupus nephritis (kidney disease associated with a multisystem autoimmune disease, systemic lupus erythematosus), as well as several skin diseases, e.g., dermititis herpetiformis (presence of vesicles on the skin that burn and itch), and pemphigus vulgaris (large vesicles on the skin). Other diseases in which the alternate pathway of complement activation has been implicated include rheumatoid arthritis, sickle cell anemia, and gram-negative bacteremia.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that the properdin factor B immunological test system be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, stability, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily.

Complement is a group of about 20 different proteins that are activated by antibodies that have reacted with their

corresponding antigen (that substance that caused the antibodies to be produced by the body). The classical pathway of complement activation begins with components C_1, C_2, C_3, and C_4, and ends with components C_5, C_6, C_7, C_8, and C_9, which cause the lysis (destruction) of cells that are foreign to the body, e.g., bacteria. The alternative to the classical pathway of complement activation does not require antibodies or the first few components of complement, C_1, C_2, and C_4, for activation. Certain components of bacterial cell walls and similar substances can cause the activation of complement beginning with component C_3 in combination with properdin factor B. In this situation, C_3 and properdin factor B are deposited on bacterial cells or body tissues (in the case of malfunctions of the immunologic system). The activation of the alternate pathway of complement activation can be detected in patient serum by a depression in the amount of properdin factor B, C_3, and the other final complement components concomitant with normal values of C_4 and the primary complement components. The measurement of the contribution of the alternate pathway of complement activation to a disease process may aid in the diagnosis of several kidney and skin diseases, as well as rheumatoid arthritis, sickle cell anemia, and gram-negative bacterial infections.

The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, stability, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1, 2, and 3).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of immunologic disorders. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that properdin factor B immunological test systems be classfied into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Cooper, N. R., "The Complement System" *in* "Basic and Clinical Immunology," Lange Medical Publications, Edited by H. H. Fudenberg, D. P. Stities, J. L. Caldwell, and J. V. Wells, Los Altos, CA, pp. 58–69, 1976.

2. Götze, O. and H. J. Mueller-Eberhard, "The Alternative Pathway of Complement Activation," *Advances in Immunology*, 24:1–35, 1976.

3. Tucker, E. S., "The Role of Complement and Other Biochemical Mediators in Immunologic Disease" *in* "Immunopathology, Clinical Laboratory Concepts and Methods," Little, Brown and Co., Boston, pp. 104–131, 1974.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5340, to read as follows:

§ 866.5320 Properdin factor B immunological test system.

(a) *Identification.* A properdin factor B immunological test system is a device that consists of the reagents used to measure by immunological techniques properdin factor B in serum and body fluids. The deposition of properdin factor B in body tissues or a corresponding depression in the amount of properdin factor B in serum and body fluids is evidence of the involvement of the alternative to the classical pathway of activation of complement (a group of plasma proteins which cause the destruction of cells which are foreign to the body). Measurement of properdin factor B adds in the diagnosis of several kidney diseases, e.g., chronic glomerulonephritis (inflammation of the glomeruli of the kidney), lupus nephritis (kidney disease associated with a multisystem autoimmune disease, systemic lupus erythematosus), as well as several skin diseases, e.g., dermititis herpetiformis (presence of vesicles on the skin that burn and itch), and pemphigus vulgaris (large vesicles on the skin). Other diseases in which the alternate pathway of complement activation has been implicated include rheumatoid arthritis, sickle cell anemia, and gram-negative bacteremia.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11854 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2240]

Medical Devices; Classification of Factor XIII, A, S, Immunological Test Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying factor XIII, A, S, immunological test systems into class I (general controls). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the

development of the proposed regulation. The immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of factor XIII, A, S, immunological test systems:

1. Identification: A factor XIII, A, S, immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the factor XIII (a blood-clotting factor), in platelets (A) or serum (S). Measurements of factor XIII, A, S, aid in the diagnosis of certain bleeding disorders resulting from a deficiency of this factor.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that the factor XIII, A, S, immunological test system be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device. Absence of coagulation factor XIII is rare and results in bleeding disorders and problems in wound healing. Congenital deficiencies are inherited, but acquired deficiencies occur in liver disorders and in the presence of circulating inhibitors.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that Factor XIII, A, S, immunological test systems be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5330, to read as follows:

§ 866.5330 Factor XIII, A, S, immunological test system.

(1) *Identification:* A factor XIII, A, S, immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the factor XIII (a blood-clotting factor), in platelets (A) or serum (S). Measurements of factor XIII, A, S, aid in the diagnosis and treatment of certain bleeding disorders resulting from a deficiency of this factor.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980 submit to the hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11855 Filed 4–21–80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 866

[Docket No. 78N–2241]

Medical Devices; Classification of Ferritin Immunological Test Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying ferritin immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of ferritin immunological test systems:

1. Identification: A ferritin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the ferritin (an iron-storing protein) in serum and body fluids. Measurements of ferritin aid in the diagnosis of diseases affecting iron metabolism, such as hemochromatosis (iron overload) and iron deficiency anemia.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that the ferritin immunological test system be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, stability, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Ferritin is the major iron-storage protein of the body. Several different molecular forms are found in all tissues of the body. Large amounts of ferritin are found in the red-blood-cell forming organs (liver, spleen, and bone marrow). Very small amounts have been demonstrated as a normal constitutent of plasma or serum. In clinical disorders of iron imbalance, the levels of plasma ferritin may reflect the levels of iron stored in the body. Elevated levels of serum ferritin have been found in liver disease and in increased red cell turnover (Ref. 6). In iron deficiency anemia, low levels of plasma ferritin have been found. However, the usefulness of the serum ferritin test may be limited when a deficiency coexists with inflammatory or malignant conditions, because ferritin levels in serum may be within the normal range. Under these conditions, caution must be observed in the interpretation of the results. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, stability, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical

experience with, the device and upon a review of the literature (Refs. 1 through 6).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of diseases affecting the iron metabolism, such as hemochromatosis (iron overload) and iron deficiency anemia. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that ferritin immunological test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Jacobs, A. and M. Worwood, "Ferritin in Serum; Clinical and Biochemical Implications," *New England Journal of Medicine,* 292:951–956, 1975.

2. Wands, J. R. et al., "Normal Serum Ferritin Concentrations in Precirrhotic Hemochromatosis," *New England Journal of Medicine,* 294:302–305, 1976.

3. Crosby, W. H., "Serum Ferritin Fails to Indicate Hemochromatosis—Nothing Gold Can Stay," *New England Journal of Medicine,* 294:333–334, 1976.

4. Crosby, W. H., "Normal Serum Ferritin in Precirrhotic Hemochromatosis," *New England Journal of Medicine,* 296(19):1116, 1977.

5. Fairbanks, V. F. and E. Beutler, "Iron Metabolism," *in hematology,* 2d Ed., Edited by Williams, W., E. Butler, A. Erslev, and R. W. Rundles, McGraw Hill, pp. 168–177, 1977.

6. Lipschitz, D. A., J. D. Cook, and C. A. Finch, "A Clinical Evaluation of Serum Ferritin as an Index of Iron Stores," *New England Journal of Medicine,* 290(22):1213–1216, 1974.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5340, to read as follows:

§ 866.5340 Ferritin immunological test system.

(a) *Identification.* A ferritin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the ferritin (an ironstoring protein) in serum and body fluids. Measurements of ferritin aid in the diagnosis of diseases affecting iron metabolism, such as hemochromatosis (iron overload) and iron deficiency anemia.

(b) *Classification.* Class II (performance standards).

Interested perons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11856 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2242]

Medical Devices; Classification of Fibrinopeptide A Immunological Test Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying fibrinopeptide A immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of fibrinopeptide A immunological test systems:

1. Identification: A fibrinopeptide A immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the fibrinopeptide A (a blood-clotting factor) in plasma and body fluids. Measurement of fibrinopeptide A may aid in the diagnosis and treatment of certain blood-clotting disorders.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the fibrinopeptide A immunological test system be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, specificity, sensitivity, and stability, and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Fibrinogen is essential for the formation of blood clots because it is the substance from which the clot is formed. The enzyme thrombin converts fibrinogen into fibrinopeptide A, fibrinopeptide B, and the fibrin monomer, which combine chemically with other fibrin molecules to form a blood clot. Measurement of fibrinopeptide A can be used as a tool for studying thrombin activity in vitro. Significantly increased levels of fibrinopeptide A have been seen in patients with venous thrombosis (blood clot) and/or pulmonary embolism (clot in lung). Following heparin therapy (administration of the anticoagulant heparin, intravenously), levels of fibrinopeptide A have been shown to decline, indicating that measurement of fibrinopeptide A may be useful to monitor

clotting therapy. Fibrinogen and fibrinogen derivatives containing fibrinopeptide A have been shown to cross-react in immunochemical assays, and therefor fibrinopeptide A must be extracted before assay. The Panel believes that general controls will not provide sufficient control over the device's accuracy, precision, sensitivity, specificity, and stability. The Panel believes that a performance standard will provide a reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of the data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1 and 2).

5. Risks to Health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of blood-clotting disorders. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that fibrinopeptide A immunological test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons from 9 a.m. to 4 p.m., Monday through Friday.

1. Gerrits, W. B. J., O. T. N. Flier, and J. van der Meer, "Fibrinopeptide A Immunoreactivity in Human Plasma," *Thrombosis Research*, 5(2):197–212, 1974.

2. Nossel, H., V. P. Butler, R. E. Canfield, I. Yudelman, M. Kalliope Spanondis, and T. Soland, "Potential Use of Fibrinopeptide A Measurement in the Diagnosis and Management of Thrombosis," *Thrombosis et Diathesis Haemorrhagica*, 33(3):426–434, 1975.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5350, to read as follows:

§ 866.5350 Fibrinopeptide A immunological test system.

(a) *Identification.* A fibrinopeptide A immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the fibrinopeptide A (a blood-clotting factor) in plasma and body fluids. Measurement of fibrinopeptide A may aid in the diagnosis and treatment of certain blood-clotting disorders.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11857 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2243]

Medical Devices; Classification of Cohn Fraction IV Immunological Test Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying Cohn fraction IV immunological test systems into class I (general controls). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the Office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Srikrishna Vadlamudi, Bureau of Medical Devices (HFA–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of Cohn fraction IV immunological test systems:

1. Identification: A Cohn fraction IV immunological test system is a device that consists of or measures that fraction of plasma proteins, predominantly *alpha-* and *beta-*globulins, used as a raw material for the production of pure *alpha-* or *beta-*globulins. Measurement of specific *alpha-* or *beta-*globulins aids in the diagnois of many diseases, such as Wilson's disease (an inherited disease affecting the liver and brain), Tangier's disease (absence of Alpha-1-lipoprotein), malnutrition, iron deficiency anemia, red blood cell disorders and kidney disease.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that the Cohn fraction IV immunological test systems be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The device is produced by a simple process, i.e., fractional precipitation of plasma proteins with ethanol at low temperature and moderately low pH (hydrogen-ion concentration).

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that Cohn fraction IV immunological test systems be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficent to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5360, to read as follows:

§ 886.5360 Cohn fraction IV immunological test system.

(a) *Identification.* A Cohn fraction IV immunological test system is a device that consists of or measures that fraction of plasma proteins, predominantly *alpha-* and *beta-*globulins, used as a raw material for production of pure *alpha-* or *beta-*globulins. Measurement of specific *alpha-* or *beta-*globulins aids in the diagnosis of many diseases, such as Wilson's disease (an inherited disease affecting the liver and brain), Tangier's disease (absence of alpha-1-lipoprotein), malnutrition, iron-deficiency anemia, red blood cell disorders and kidney disease.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11858 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2244]

Medical Devices; Classification of Cohn Fraction V Immunological Test Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying Cohn Fraction V immunological test systems into class I (general controls). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Srikrishna Vadlamudi, Bureau of Medical Devices (HFA–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of fraction V immunological test systems:

1. Identification: A Cohn fraction V immunological test system is a device that consists of or measures that fraction of plasma containing predominantly albumin (a plasma protein). This test aids in the diagnosis of diseases where albumin levels may be depressed, e.g., nephrosis (disease of the kidney), proteinuria (protein in the urine), gastroenteropathy (disease of the stomach and small intestine), rheumatoid arthritis, and viral hepatitis.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that the Cohn fraction V immunological test system be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The device is produced by a simple process, i.e., fractional precipitation of plasma proteins with ethanol at low temperature and low pH (hydrogen-ion concentration).

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that Cohn fraction V immunological test systems be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficent to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5370, to read as follows:

§ 866.5370 Cohn fraction V immunological test system.

(a) *Identification.* A Cohn fraction V immunological test system is a device that consists of or measures that fraction of plasma containing predominantly albumin (a plasma protein). This test aids in the diagnosis of diseases where albumin levels may be depressed, e.g., nephrosis (disease of the kidney), proteinuria (protein in the urine), gastroenteropathy (disease of he stomach and small intestine), rheumatoid arthritis, and viral hepatitis.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (JFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11859 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2245]

Medical Devices; Classification of Free Secretory Component Immunological Test Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying free secretory component immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal became effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Depatment of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of free secretory component immunological test systems:

1. Identification: A free secretory component immunological test system is a device that consists of the reagents used to measure by immunochemical techniques free secretory component (normally a portion of the secretory IgA antibody molecule) in human body fluids. Measurement of free secretory component (protein molecules) aids in the diagnosis of persons with repetitive lung infections and other hypogammaglobulinemic conditions (low antibody levels).

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that the free secretory component immunological test systems be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, stability, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Measurement of free secretory component aids in the evaluation of patients in whom recurrent pulmonary infections or other hypogammaglobulinemic conditions produce a spectrum of infectious diseases. Several studies (Refs. 1 and 3) have shown that there is a high degree of correlation between elevated levels of free secretory component at mucosal surfaces and disease, such as recurrent pulmonary infections. Free secretory component has been detected using radioimmunoassay. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, stability, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1 through 6).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of persons with recurrent pulmonary infections. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that free secretory component immunological test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The agency believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Strober, W., et al., "Secretory Component Deficiency, a Disorder of the IgA Immune System," *The New England Journal of Medicine,* 294(7) :351–356, 1976.

2. Tourville, D. R., R. H. Adler, J. Bienenstock, T. B. Tomasi, Jr., "The Human Secretory Immunoglobulin System: Immunohistological Localization of Gamma A, Secretory "Piece," and Lactoferrin in Normal Human Tissues," *Journal of Experimental Medicine,* 129:411–429, 1969.

3. Tomasi, T. B., Jr. and J. Bienenstock "Secretory Immunoglobins," *Advances in Immunology,* 9:1–96, 1968.

4. Eidelman, S., "Some Immunological Factors in Small Intestine Disease," *The American Journal of Clinical Nutrition,* 21(9):1110–1114, 1968.

5. O'Reilly, R. J., L. Lee, and B. G. Welch, "Secretory IgA Antibody Responses to *Neisseria gonorrhoeae* in the Genital Secretions of Infected Females," *The Journal of Infectious Diseases,* 133(2):113–125, 1976.

6. Bull, D. M., and T. B. Tomasi, "Deficiency of Immunoglobulin A in Intestinal Disease," *Gastroenterology,* 54(2):313–320, 1968.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5380, to read as follows:

§ 866.5380 Free secretory component immunological test system.

(a) *Identification:* A free secretory component immunological test system is a device that consists of the reagents used to measure by immunochemical techniques free secretory component (normally a portion of the secretory IgA antibody molecule) in human body fluids. Measurement of free secretory component (protein molecules) aids in the diagnosis of persons with repetitive lung infections and other hypogammaglobulinemic conditions (low antibody levels).

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner fo Regulatory Affairs.

[FR Doc. 11860 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

21 CFR Part 866

[Docket No. 78N-2246]

Medical Devices; Classification of Alpha Globulin Immunological Test Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying alpha globulin immunological test systems into class I (general controls). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Srikrishna Vadlamudi, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of alpha globulin immunological test systems:

1. Identification: An alpha globulin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the alpha globulin (a serum protein) in serum and other body fluids. Measurements of alpha globulin may aid in the diagnosis of inflammatory lesions, infections, severe burns, and a variety of other conditions.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that the alpha globulin immunological test system be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. A decrease in alpha globulin occurs in conditions in which other serum mucoproteins are diminished, but this is not always demonstrable. An increase may occur in conditions characterized by an increase in alpha-2-globulin, such as inflammatory lesions, infections, severe burns, myocardial infarction (heart disease), extensive malignancy, rheumatoid arthritis, and other conditions.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that alpha globulin immunological test systems be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5400, to read as follows:

§ 866.5400 Alpha globulin immunological test system.

(a) *Identification.* An alpha globulin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the alpha globulin (a serum protein) in serum and other body fluids. Measurement of alpha globulin may aid in the diagnosis of inflammatory lesions, infections, servere burns, and a variety of other conditions.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-11861 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 866

[Docket No. 78N-2247]

Medical Devices; Classification of Alpha-1-Glycoproteins Immunological Test Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying alpha-1-glycoproteins immunological test systems into class I (general controls). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Srikrishna Vadlamudi, Bureau of Medical Devices (HFA-440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of alpha-1-glycoproteins immunological test systems:

1. Identification: An alpha-1-glycoproteins immunological test system is a device that consists of the reagents used to measure by immunochemical techniques alpha-1-glycoproteins (a group of plasma proteins found in the alpha-1 group when subjected to electrophoresis) in serum and other body fluids. Measurement of specific alpha-1-glycoproteins may aid in the diagnosis of collagen (connective tissue) disorders, tuberculosis, infections, extensive malignancy, and diabetes.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that the alpha-1-glycoproteins immunological test system be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that alpha-1-glycoproteins immunological test systems be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficent to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5420, to read as follows:

§ 866.5420 Alpha-1-glycoproteins immunological test system.

(a) *Identification.* An alpha-1-glycoproteins immunological test system is a device that consists of the reagents used to measure by immunochemical techniques alpha-1-glycoproteins (a group of plasma proteins found in the alpha-1 group when subjected to electrophoresis) in serum and other body fluids. Measurement of specific alpha-1-glycoproteins may aid in the diagnosis of collagen (connective tissue) disorders, tuberculosis, infections, extensive malignancy, and diabetes.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11862 Filed 4–21–80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 866

[Docket No. 78N–2248]

Medical Devices; Classification of Alpha-2-Glycoproteins Immunological Test Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying alpha-2-glycoproteins immunological test systems into class I (general controls). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of alpha-2-glycoproteins immunological test systems:

1. Identification: An alpha-2-glycoproteins immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the alpha-2-glycoproteins (a group of plasma proteins found in the alpha-2 group when subjected to electrophoresis) in serum and other body fluids. Measurement of alpha-2-glycoproteins aids in the diagnosis of some cancers and genetically-inherited deficiencies of these plasma proteins.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that the alpha-2-glycoprotein immunological test systems be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that alpha-2-glycoproteins immunological test systems be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5425, to read as follows:

§ 866.5425 Alpha-2-glycoproteins immunological test system.

(a) *Identification.* An alpha-2-glycoproteins immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the alpha-2-glycoproteins (a group of plasma proteins found in the alpha-2 group when subjected to electrophoresis) in serum and other body fluids. Measurement of alpha-2-glycoproteins aids in the diagnosis of some cancers and genetically-inherited deficiencies of these plasma proteins.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing

Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11863 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2249]

Medical Devices; Classification of Beta-2-Glycoprotein I Immunological Test Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying beta-2-glycoprotein I immunological test systems into class I (general controls). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of beta-2-glycoprotein I immunological test systems:

1. Identification: A beta-2-glycoprotein I immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the beta-2-glycoprotein I (a serum protein) in serum and other body fluids. Measurement of beta-2-glycoprotein I aids in the diagnosis of an inherited deficiency of this serum protein.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that the beta-2-glycoprotein I immunological test systems be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that beta-2-glycoprotein I immunological test systems be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5430, to read as follows:

§ 866.5430 Beta-2-glycoprotein I immunological test system.

(a) *Identification.* A beta-2-glycoprotein I immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the beta-2-glycoprotein I (a serum protein) in serum and other body fluids. Measurement of beta-2-glycoprotein I aids in the diagnosis of an inherited deficiency of this serum protein.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11864 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2250]

Medical Devices; Classification of Beta-2-Glycoprotein III Immunological Test Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying beta-2-glycoprotein III immunological test systems into class I (general controls). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of beta-2-glycoprotein III immunological test systems:

1. Identification: A beta-2-glycoprotein III immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the beta-2-glycoprotein III (a serum protein) in serum and other body fluids. Measurement of beta-2-glycoprotein III aids in the diagnosis of an inherited deficiency of this serum protein and a variety of other conditions.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that the beta-2-glycoprotein III immunological test system be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. An increase in serum glycoproteins occurs in various acute and chronic conditions, e.g., malignant neoplasm (cancer), collagen disease (wasting disease), tuberculosis, diabetes mellitus, gout, and liver disease. However, the nonspecificity of increased serum glycoproteins has limited its usefulness in clinical diagnosis.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that beta-2-glycoprotein III immunological test systems be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5440, to read as follows:

§ 866.5440 Beta-2-glycoprotein III immunological test system.

(a) *Identification.* A beta-2-glycoprotein III immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the beta-2-glycoprotein III (a serum protein) in serum and other body fluids. Measurement of beta-2-glycoprotein III aids in the diagnosis of an inherited deficiency of this serum protein and a variety of other conditions.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11865 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2251]

Medical Devices; Classification of Haptoglobin Immunological Test Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying haptoglobin immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of haptoglobin immunological test systems:

1. Identification: A haptoglobin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the haptoglobin (a protein that binds hemoglobin, the oxygen-carrying pigment in red blood cells) in serum. Measurement of haptoglobin may aid in the diagnosis of hemolytic diseases (diseases in which the red blood cells rupture and release hemoglobin) related to the formation of hemoglobin-haptoglobin complexes and certain kidney diseases.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that the haptoglobin immunological test system be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, stability, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Haptoglobins are a group of closely related glycoproteins (proteins with a covalently attached carbohydrate group) that bind to the protein portions of hemoglobin. Haptoglobins are inherited (genetically controlled) serum glycoproteins. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, stability, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of the data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1 through 4).

5. Risks to Health: Misdiagnosis and inappropriate therapy: Failure of the device

to perform satisfactorily may lead to an error in the diagnosis of the cause of red blood cell hemolysis and kidney. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that haptoglobin immunological test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (HFA–305) (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Atwater, J. and A. J. Erslev, "Haptoglobin Assay" *in* "Hematology," Edited by W. J. Williams et al., McGraw Hill, New York, pp. 1384–1386, 1972.

2. Bacchus, H., "Serum Glycoproteins and Malignant Neoplastic Disorders," CRC Critical Reviews in Clinical Laboratory Sciences, pp. 333–362, December 1977.

3. Davidson, I. and D. Nelson, "The Blood" *in* "Clinical Diagnosis by Laboratory Methods," Edited by Davidson, J. Henry and W. B. Saunders, 15th Ed., Philadelphia, Pa., p. 186, 1974.

4. Ramakers, J. M. and H. J. H. Kreutzer, "Turbidimetric Determination of Haptoglobin," *Journal of Clinical Chemistry and Clinical Biochemistry*, 14(8):407–410, 1976.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5460, to read as follows:

§ 866.5460 Haptoglobin immunological test system.

(a) *Identification.* A haptoglobin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the haptoglobin (a protein that binds hemoglobin, the oxygen-carrying pigment in red blood cells) in serum. Measurement of haptoglobin may aid in the diagnosis of hemolytic diseases (diseases in which the red blood cells rupture and release hemoglobin) related to the formation of hemoglobin-haptoglobin complexes and certain kidney diseases.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11866 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2252]

Medical Devices; Classification of Hemoglobin Immunological Test Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying hemoglobin immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Springs, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of hemoglobin immunological test systems:

1. Identification: A hemoglobin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the different types of free hemoglobin (the oxygen-carrying pigment in red blood cells) in blood, urine, plasma, or other biological fluids. Measurement of free hemoglobin aids in the diagnosis of patients with various hematologic disorders, such as sickle cell anemia, Fanconi's anemia (a rare inherited disease), aplastic anemia (bone marrow does not produce enough blood cells), and leukemia (cancer of the blood-forming organs).

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that hemoglobin immunological test systems be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, stability, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The red blood cells of normal adult blood contain a mixture of three structurally different hemoglobin (Hb) molecules. Increased or decreased amounts of one or more of the hemoglobins are found in some hematologic diseases, and the measurement of hemoglobins, e.g., Ao, A1, A2, Fo, S, C, has important diagnostic applications. Increased levels of Hb–Fo are often found in patients with Fanconi's anemia, aplastic anemia, sickle cell anemia, and leukemia (cancer of bloodforming organs). The precent of Hb–A2 is increased in patients with beta-thalassemia trait (a hereditary hemolytic anemia caused by diminished synthesis of the beta-polypeptide chain of hemoglobin) and decreased in individuals with hereditary persistence of fetal hemoglobin (a form of hemoglobin constituting 50 percent of fetal hemoglobin, but found in small amounts in adults) (Ref. 1). Radioimmunoassay is the preferred method for measuring the various hemoglobins. The device may be used for prenatal diagnosis of hemoglobinopathies (a hemolytic disorder characterized by hemoglobin abnormality)

and for microanalysis of blood samples for legal purposes such as paternity determinations or evidence of involvement in a crime. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, stability, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1 through 4).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of hematologic disorders such as anemia or luekemia. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that hemoglobin immunological test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency believes that there is sufficient information to establish a performance standard for the device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Garver, F. A. et al., "Specific Radioimmunochemical Identification and Quantitation of Hemoglobins A2 and F," *American Journal of Hematology,* 1:459–469, 1976.

2. Rowley, P. T. et al., "Sickle Hemoglobin; A Specific Radioimmunoassay," *Blood,* 43(4):607–611, 1974.

3. Boerma, F. W. and T. H. J. Huisman, "Serologic Investigations of Human Hemoglobins, II. Antibodies Produced by Isolated Human Hemoglobin Types With Known Structural Differences," *Journal of Laboratory and Clinical Medicine,* 63(2):264–278, 1964.

4. Goodman, M. and D. H. Campbell, "Differences in Antigenic Specificity of Human Normal Adult, Fetal, and Sickle Cell Anemia Hemoglobin," *Blood,* 8:422–433, 1953.

Therefore, under the Federal Food, Drug, and Cosmetic Act secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866,5470, to read as follows:

§ 866.5470 Hemoglobin immunological test system.

(a) *Identification.* A hemoglobin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the different types of free hemoglobin (the oxygen-carrying pigment in red blood cells) in blood, urine, plasma, or other biological fluids. Measurements of free hemoglobin aids in the diagnosis of patients with various hematologic disorders, such as sickle cell anemia, Fanconi's anemia (a rare inherited disease), aplastic anemia (bone marrow does not produce enough blood cells), and leukemia (cancer of the blood-forming organs).

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11867 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2253]

Medical Devices; Classification of Hemolytic Immunological Test Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying hemolytic immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of hemolytic immunological test systems:

1. Identification: A hemolytic immunological test system is a device that consists of the reagents used to measure by immunochemical techniques immunoglobulins and C_3 (the third component of complement) attached to the surface of a patient's red blood cells. Measurement of immunoglobulins and C_3 on the surface of red blood cells aids in the diagnosis of hemolytic transfusion reactions (red cell destruction that results from a patient's receiving blood from a noncompatible donor), hemolytic disease of the newborn (destruction of the red blood cells of an Rh+ fetus of an RH− mother), immune drug-induced hemolytic anemia, such as a reaction to penicillin, as well as many autoimmune hemoytic anemias (destruction of red cells by the body's own antibodies) associated with chronic lymphocytic leukemia (cancer of the white blood cells), lymphoma (cancer of lymphoid tissues), systemic lupus erythematosus (a multisystem autoimmune disease), or paroxysmal nocturnal hemoglobinuria (hemoglobin in the urine).

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that the hemolytic immunological test system be classified into class II (performance

standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, specificity, sensitivity, and stability and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. When a patient has antibodies present in his/her system that react with some component on the surface of his/her own red blood cells, these antibodies attach to the surface of the red blood cell. If there is enough antibody on the red blood cell that can fix complement (plasma proteins that cause destruction of red cells and bacteria), components of complement including C_3 (the third complement component) also attach to the red cells. The presence of large amounts of complement on the surface of a red blood cell may cause the destruction of the red blood cell. Differential diagnosis of the many hemolytic anemias depends upon whether either or both immunoglobulin or C_3 are present on the red cell surface, and upon the temperature at which these substances can be detected. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, stability, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1 through 4). Properdin factor B is a protein derived by enzyme activity from a component of the complement system. The properdin is a group of proteins involved in resistance to infection and is similar to, but distinct from, complement. The properdin hemolytic system has been implicated in instances of the human disease known as paroxysmal nocturnal hemoglobinuria (hemoglobin in urine). Measurement of complement components C_3 and C_4 and of Properdin Factor B gives an estimate of the contribution which the alternative pathway of complement activation rather than the classical complement activation system may have in a given disease process. This determination is useful in evaluation of anemias, chronic glomerulonephritis (inflammation of the glomeruli of the kidney), and certain other disorders of inflammation and infection. (Refs. 1 through 4).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of hemotologic disorders and some disorders of inflammation and infection. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that hemolytic immunological test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Gotze, O. and H. J. Muller-Eberhard, "The Alternative Pathway of Complement Activation," *Advances in Immunology, 24:1–35, 1976.*

2. Tucker, E. S., "The Role of Complement and Other Biochemical Mediators in Immunologic Disease," *in* "Immunopathology-Clinical Laboratory Concepts and Methods," Edited by R. H. Nakamura, Little, Brown and Co., pp. 104–131, 1974.

3. Shulman, N. R., "Analyses of Drug Antibodies with Autoimmune Implications," *in* "Laboratory Diagnosis of Immunologic Disorders," Edited by G. N. Vyas, D. P. Stites, and G. Brecher, Grune and Stratton pp. 31–46, 1975.

4. Petz, L. D. and G. Garratty, "Laboratory Correlations in Immune Hemolytic Anemias," *in* "Laboratory Diagnosis of Immunologic Disorders," Edited by G. N. Vyas, D. P. Stites, and B. Brecher, Grune and Stratton, pp. 139–153, 1975.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5480, to read as follows:

§ 866.5480 Hemolytic immunological test system.

(a) *Identification.* A hemolytic immunological test system is a device that consist of the reagents used to measure by immunochemical techniques immunoglobulines and C_3 (the third component of complement) attached to the surface of a patient's red blood cells. Measurement of immunoglobulins and C_3 on the surface of red blood cells aids in the diagnosis of hemolytic transfusion reactions (red cell destruction that results from a patient's receiving blood from a noncompatible donor), hemolytic disease of the newborn (destruction of the red blood cells of an Rh+ fetus of an Rh− mother), immune drug-induced hemolytic anemia, such as a reaction to penicillin, as well as maney autoimmune hemolytic anemias (destruction of red cells by the body's own antibodies) associated with chronic lymphocytic leukemia (cancer of the white blood cells), lymphoma (cancer of lymphoid tissues), systemic lupus erythematosus (a multisystem autoimmune disease), or paroxysmal nocturnal hemoglobinuria (hemoglobin in the urine).

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980 submit to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11868 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2254]

Medical Devices; Classification of Hemopexin Immunological Test Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying hemopexin immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30

days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of hemopexin immunological test systems:

1. Identification: a hemopexin immunological test system is a device that consists of the reagents used to measure by immunchemical techniques the hemopexin (a serum protein that binds heme, a component of hemoglobin) in serum. Measurement of hemopexin aids in the diagnosis of various hematologic disorders, such as hemolytic anemia (anemia due to shortened in vivo survival of mature red blood cells and inability of the bone marrow to compensate for their decreased life span) and sickle cell anemia.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the hemopexin immunological test system be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, stability, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unneccessarily. Hemopexin is a glycoprotein synthesized in the liver; its major function is the binding of heme (a component of hemoglobin). Serum hemopexin levels are decreased in conditions of intravascular hemolysis (internal bleeding) and anemias such as thallasemia major, sickle cell, and pernicious anemia (diseases affecting functioning of red blood cells). Increased levels of hemopexin have been reported in patients with inflammatory conditions and various types of cancer. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensivity, stability, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based. The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1 and 2).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of hematologic disorders such as hemolytic anemia, intravascular hemolysis, or sickel cell anemia. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that hemopexin immunological test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The agency believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Bacchus, H., "Serum Glycoproteins and Malignant Neoplastic Disorders," *CRC Critical Reviews in Clinical Laboratory Sciences*, p. 356, Dec. 1977.

2. Wintrobe, M. et al., "Clinical Hematology," 7th Ed. Lea and Febringer, Publishers, Philadelphia, Pa., p. 730, 1974.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5490, to read as follows:

§ 866.5490 Hemopexin immunological test system.

(a) *Identification.* A hemopexin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the hemopexin (a serum protein that binds heme, a component of hemoglobin) in serum. Measurement of hemopexin aids in the diagnosis of various hematologic disorders, such as hemolytic anemia (anemia due to shortened in vivo survival of mature red blood cells and inability of the bone marrow to compensate for their decreased life span) and sickle cell anemia.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11869 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2255]

Medical Devices; Classification of Hypersensitivity Pneumonitis Immunological Test Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying hypersensitivity pneumonitis immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After Considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of hypersensitivity pneumonitis immunological test systems:

1. Identification: A hypersensitivity pneumonitis immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the immunoglobulin antibodies which react specifically with organic dust derived from fungal or animal protein sources. When these antibodies react with such dusts in the lung, immune complexes precipitate and trigger an inflammatory reaction (hypersensitivity pneumonitis). Measurement of these immunoglobulin G antibodies aid in the diagnosis of hypersensitivity pneumonitis and other allergic respiratory disorders.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that the hypersensitivity pneumonitis immunological test system be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, stability, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Hypersensitivity pneumonitis is an allergic respiratory disorder. The precipitating antibodies which cause the condition may be formed against organic dusts derived from fungal or animal proteins. Regardless of the inciting organic dust, the clinical symptoms remain essentially the same: cough, shortness of breath, fever, and chills. Immunofluorescent studies of human lung biopsy specimens of affected persons have provided histological evidence of IgG, IgM, and complement (immune complexes) as well as an intense infiltration of inflammatory cells in the alveolar (blood gas exchange) area of the lung. The immunologic diagnosis of extrinsic allergic alveolitis (inflammation of the lungs) is based on the detection of immune complexes present in the alveolar area of the lung. Hypersensitivity pneumonitis and other pulmonary diseases with immunological features must be distinguished from bronchial asthma for correct treatment. The causal antibodies may be detected by various methods, including skin tests, agar gel diffusion, indirect immunofluorescence, or rocket electrophoresis. The Panel believes the general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, stability, and specificity. The Panel believes that a performance standard will profile reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1 through 4).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of hypersensitivity pneumonitis (an allergic respiration disorder). Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that hypersensitivity pneumonitis immunological test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Pepys, J., "Pulmonary Hypersensitivity Disease due to Inhaled Organic Antigens," *Annals of Internal Medicine, 64:943–948, 1966.*

2. Ghose, T., P. Landrigan, R. Killeen, and J. Dill, "Immunopathological Studies in Patients With Farmer's Lung," *Clinical Allergy,* 4:119–129, 1974.

3. Wenzel, F. J., D. A. Emanuel, and B. R. Lawton, "Pneumonitis due to Micromonospora Vulgaris (Farmer's Lung," *American Review of Respiratory Diseases,* 95:652–655, 1967.

4. Pepys, J. and P. A. Jenkins, "Precipitin (FLH) Test in Farmer's Lung," *Thorax,* 20:21–35, 1965.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5500, to read as follows:

§ 866.5500 Hypersensitivity pneumonitis immunological test system.

(a) *Identification.* A hypersensitivity pneumonitis immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the immunoglobulin antibodies which react specifically with organic dust derived from fungal or animal protein sources. When these antibodies react with such dusts in the lung, immune complexes precipitate and trigger an inflammatory reaction (hypersensitivity pneumonitis). Measurement of these immunoglobulin G antibodies aid in the diagnosis of hyper-sensitivity pneumonitis and other allergic respiratory disorders.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11870 Filed 2–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2256]

Medical Devices; Classification of Immunoglobulins A, G, M, D, and E Immunological Test Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying immunoglobulins A, G, M, D, and E immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class II. The effect of classifying a

device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of immunoglobulins A, G, M, D, and E immunological test systems.

1. Identification: An immunoglobulins A, G, M, D, and E immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the immunoglobulins A, G, M, D, and E (serum - antibodies) in serum. Measurement of these immunoglobulins aids in the diagnosis of abnormal protein metabolism and the body's lack of ability to resist infectious agents.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that immunoglobulins A, G, M, D, and E immunological test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, specificity, sensitivity, and stability, and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, specificity, sensitivity, and stability. The Panel believes that a standard will provide a reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a review of the literature (Refs. 1 through 8). Scientists have established through repetitious testing of the same persons that normal persons vary as much as plus or minus 11 percent in levels of immunoglobulins A, G, M, D, and E; and the expected or inherent laboratory precision variability for this test system has been estimated at plus or minus 6 percent (Ref. 5). Three separate evaluations of the accuracy and sensitivity of five manufacturers' immunoglobulin test kits (using 12 serum specimens) revealed variations of 100 percent in the expected test results (Refs. 1 through 3). The Panel noted that the Internation Union of Immunological Societies under the World Health Organization is developing standards for the various immunoglobulins. (Ref. 8).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of the ability of the body to resist infectious agents and in the diagnosis of abnormal protein metabolism. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that immunoglobulins A, G, M, D, and E immunological test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by this device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Berne, B. H., "Differing Methodology and Equations Used in Quantitating Immunoglobulins by Radial Immunodiffusion—a Comparative Evaluation of Reported and Commercial Techniques," *Clinical Chemistry,* 20(1): 61–69, 1974.

2. Center for Disease Control, "Proficiency Testing Summary Analysis, Diagnostic Immunology," U.S. Department of Health, Education, and Welfare, Public Health Service, Atlanta, GA, April 1978.

3. Davis, N. C. and M. Ho, "Quantitation of Immunoglobulins" *in* "Manual of Clinical Immunology," Edited by N. R. Rose and H. Friedman, ASM, Washington, DC, pp. 4–16, 1976.

4. Fahey, J. L. and E. M. McKelvey, "Quantitative Determination of Serum Immunoglobulins in Antibody-Agar Plates," *The Journal of Immunology,* 94:84–90, 1965.

5. Gilliland, B. C. and M. Mannik, "Immunologic Quantitation of Proteins in Serum, Urine, and Other Body Fluids," *in* "Laboratory Diagnosis of Immunologic Disorders," Edited by G. N. Vyas, D. P. Stites, and G. Brecher, Grune and Stratton, New York, pp. 13–30, 1975.

6. Heremans, J. F. and P. L. Masson, "Specific Analysis of Immunoglobulins: Techniques and Clinical Values," *Clinical Chemistry,* 19:294–300, 1973.

7. Hosty, T. A., M. Hollenbeck, and S. Shane. "Intercomparison of Results Obtained with Five Commercial Diffusion Plates Supplied for Quantitation of Immunoglobulins," *Clinical Chemistry,* 19:524–526, 1973.

8. Rowe, D. S., B. Grab, and S. G. Anderson, "An International Reference Preparation for Human Serum Immunoglobulins G, A, and M: Content of Immunoglobulins by Weight," *Bulletin of the World Health Organization* 46:67–79, 1972.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5510, to read as follows:

§ 866.5510 Immunoglobulins A, G, M, D, and E immunological test system.

(a) *Identification.* An immunoglobulins A, G, M, D, and E immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the immunoglobulins A, G, M, D, and E (serum antibodies) in serum. Measurement of these immunoglobulins aids in the diagnosis of abnormal protein metabolism and the body's lack of ability to resist infectious agents.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-11871 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 866

[Docket No. 78N-2257]

Medical Devices; Classification of Immunoglobulin G (Fab Fragment Specific) Immunological Test Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying immunoglobulin G (Fab fragment specific) immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Srikrishna Vadlamudi, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of immunoglobulin G (Fab fragment specific) immunological test systems:

1. Identification: An immunoglobulin G (Fab fragment specific) immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the Fab antigen-binding fragment resulting from breakdown of immunoglobulin G antibodies in urine, serum, and other biological fluids. Measurement of Fab fragments of immunoglobulin G aids in the diagnosis of lymphoproliferative disorders, such as multiple myeloma (tumor of bone marrow cells), Waldenstrom's macroglobulinemia (increased immunoglobulin production by the spleen and bone marrow cells), and lymphoma (tumor of the lymphoid tissues).

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that the immunoglobulin G (Fab fragment specific) immunological test system be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, stability, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Immunoglobulin G can be broken down into many different fragments, depending on where the break takes place in the molecule, e.g., heavy chains, light chains, Fc fragments, or Fab fragments. Fab is the antigen-binding fragment resulting from the enzymatic breakdown of immunoglobulin G antibodies. This fragment can be detected in urine or serum, usually by immunoelectrophoresis. The presence of monoclonal (homogeneous) immunoglobulin in either serum or urine is presumptive evidence for the diagnosis of lymphoproliferative disorders, e.g., multiple myeloma, Waldenstrom's macroglobulinemia and lymphoma. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, stability, and specificity. The Penal believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1 through 3).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of lymphoproliferative disorders. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that immunoglobulin G (Fab fragment specific) immunological test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by this device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Gilliand, B. C. and M. Mannik, "Immunologic Quantitation of Proteins in Serum, Urine and other Body Fluids" *in* "Laboratory Diagnosis of Immunologic Disorders," Edited by G. N. Vyas, D. P. Stites, and G. Breecher, Grune and Stratton, New York pp. 13-30, 1975.

2. Solomon, A, "Bence-Jones Proteins and Light Chains of Immunoglobulins," *New England Journal of Medicine,* 294(1):17-23, 1976.

3. Solomon, A., "Bence-Jones Proteins and Light Chains of Immunoglobulins," *New England Journal of Medicine,* 294(2):91-98, 1976.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5520, to read as follows:

§ 866.5520 Immunoglobulin G (Fab fragment specific) immunological test system.

(a) *Identification.* An immunoglobulin G (Fab fragment specific) immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the Fab antigen-binding fragment resulting from breakdown of immunoglobulin G antibodies in urine, serum, and other biological fluids. Measurement of Fab fragments of immunoglobulin G aids in the diagnosis of lymphoproliferative disorders, such as multiple myeloma (tumor of bone marrow cells), Waldenstrom's macroglobulinemia (increased immunoglobulin production by the spleen and bone marrow cells), and lymphoma (tumor of the lymphoid tissues).

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980 submit to the Hearing

Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be indentified with the Hearing Clerk Docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11872 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2258]

Medical Devices; Classification of Immunoglobulin G (FC Fragment Specific) Immunological Test Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying immunoglobulin G (Fc fragment specific) immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Srikrishna Vadlumudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of immunoglobulin G (Fc fragment specific) immunological test systems:

1. Identification: An immunoglobulin G (Fc fragment specific) immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the Fc (carbohydrate containing) fragment of immunoglobulin G (resulting from breakdown of immunoglobulin G antibodies) in urine, serum, and other biological fluids. Measurement of immunoglobulin G Fc fragments aids in the diagnosis of plasma cell antibody-forming abnormalities, e.g., gamma heavy chain disease.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that the immunoglobulin G (Fc fragment specific) immunological test system be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, stability, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Immunoglobulin G can be broken down into many different fragments, depending on where the break takes place in the molecule, e.g., heavy chains, light chains, Fab or Fc fragments. Immunochemical analysis has demonstrated the presence of gamma globulin and gamma globulin fragments in the urine of normal individuals. The immunoglobulin G Fc (carbohydrate containing) fragment may account for 15 percent of the gamma globulin present in normal urine. Gamma heavy chain disease is a relatively rare form of plasma cell abnormality characterized by the elaboration of excessive quantities of Fc fragments of IgG. Measurement of the Fc fragment of IgG requires specific and sensitive immunochemical techniques to show that it is not Bence-Jones proteins (a form of light chain fragment of immunoglobulin G excreted in the urine of myeloma patients) or any other light chain fragment. Gamma heavy chain disease resembles lymphoma with a patient having a marked susceptibility to infection. Survival from time of onset of symptoms has ranged from a few months to a few years (Refs. 1 and 2). The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, stability, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1 and 2).

5. Risks to health. Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of gamma heavy chain disease or other plasma cell abnormalities. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that immunoglobulin G (Fc fragment specific) immunological test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Deegan, M. J., "Bence Jones Proteins: Nature, Metabolism, Detection, and Significance," *Annals of Clinical and Laboratory Science,* 6(1):38–46, 1976.

2. Osserman, E., "Plasma Cell Dyscrasias," *in* "Textbook of Medicine," Edited by P. Beeson and W. McDermott, 14th Ed., W. B. Saunders & Co., Philadelphia, PA., pp. 1548–1549, 1975.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5530, to read as follows:

§ 866.5530 Immunoglobulin G (Fc fragment specific) immunological test system.

(a) *Identification.* An immunoglobulin G (Fc fragment specific) immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the Fc (carbohydrate containing) fragment of immunoglobulin G (resulting from breakdown of immunoglobulin G antibodies) in urine, serum, and other

biological fluids. Measurement of immunoglobulin G Fc fragments aids in the diagnosis of plasma cell antibody-forming abnormalities, e.g., gamma heavy chain disease.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11873 Filed 4–18–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2283]

Medical Devices; Classification of Immunoglobulin G (Fd Fragment Specific) Immunological Test Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying immunoglobulin G (Fd fragment specific) immunological test systems into class I (general controls). FDA is also publishing the recommendation of the Immumology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 Days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification panel, an FDA advisory committee, made the following recommendation regarding the classification of immunoglobulin G (Fd fragment specific) immunological test systems:

1. Identification: An immunoglobulin G (Fd fragment specific) immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the amino terminal (antigen-binding) end (Fd fragment) of the heavy chain (a subunit) of the immunoglobulin antibody molecule. Measurement of immumoglobulin G Fd fragments aids in the diagnosis of plasma antibody-forming cell abnormalities.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that the immunoglubulin G (Fd fragment specific) immunological test system be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that immunoglubulin G (Fd fragment specific) immunological test systems be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5540, to read as follows:

§ 866.5540 Immunoglobulin G (Fd fragment specific immunological test system.

(a) *Identification.* An immunoglobulin G (Fd fragment specific) immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the amino terminal (antigen-binding) end (Fd fragment) of the heavy chain (a subunit) of the immunoglobulin antibody molecule. Measurement of immunoglobulin G Fd fragments aids in the diagnosis of plasma antibody-forming cell abnormalities.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11874 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2259]

Medical Devices; Classification of Immunoglobulin (Light Chain Specific) Immunological Test Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying immunoglobulin (light chain specific) immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of immunoglobulin (light chain specific) immunological test systems:

1. Identification. An immunoglobulin (light chain specific) immunological test system is a device that consists of the reagents used to measure by immunochemical techniques both kappa and lambda types of light chain portions of immunoglobulin molecules in serum, body fluids, and tissues. In some diseases states, an excess of light chains is produced by the antibody-forming cells. These free light chains, unassociated with gamma globulin molecules, can be found in a patient's body fluids and tissues. Measurements of the various amounts of the different types of light chains aids in the diagnosis of multiple myeloma (cancer of antibody-forming cells), lymphocytic neoplasms (cancer of lymphoid tissue), Waldenstrom's macroglobulinemia (increased production of large immunoglobulins), and connective tissue diseases such as rheumatoid arthritis or systemic lupus erythematosus.

2. Recommended classification: Class II (performance standards). The Panel recommended that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that the immunoglobulin (light chain specific) immunological test system immunological test system be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, stability, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unneccessarily.

Immunoglobulin molecules normally consist of four polypeptide chains of unequal size (heavy chains and light chains) bound together by several disulfide bridges. A light chain consists of two regions, a variable region that varies with each antigen which simulates immunoglobulin synthesis, and a constant region which is characteristic of a light chain. There are two types of constant regions present in light chains, kappa and lambda.

Normally, an individual possesses a heterogeneous population of kappa and lambda light chains throughout all five classes of immunoglobulins. The urine of normal persons contains free light chains unassociated with gamma globulin molecules. Up to 50 mg of light chains may be excreted daily. Elevated levels of heterogeneous free light chains may be excreted in the urine of patients with connective tissue disease, such as rheumatoid arthritis or systemic lupus erythematosus. Free light chains of restricted heterogeneity have also been observed in urine specimens from patients with lymphocytic neoplasms. In some cancerous conditions there is a proliferation of one antibody-forming cell with excess production of light chains of one specific kind (monoclonal or homogeneous light chains).

The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensivity, stability, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1 through 4).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of multiple myeloma and other lymphoproliferative disorders. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

Proposed Classification

The agency agrees with the Panel recommendation and is proposing that immunoglobulin (light chain specific) immunological test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by this device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The agency believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Gilliland, B. and M. Mannik, "Immunologic Quantititation of Proteins in Serum, Urine, and Other Body Fluids" *in* "Laboratory Diagnosis of Immunologic Disorders," Edited by G. N. Vyas, D. P. Stites, and G. Brecher, Grune and Stratton Publishing Co., New York, pp. 13–30, 1975.

2. Solomon, A., "Bence-Jones Proteins and Light Chains of Immunoglobulins," *New England Journal of Medicine,* 294(1):17–23, 1976.

3. Solomon, A., "Bence-Jones Proteins and Light Chains of Immunoglobulins," *New England Journal of Medicine,* 294(2):91–98, 1976.

4. Deegan, M. J., "Bence-Jones Proteins Nature, Metabolism, Detection and Significance," *Annals of Clinical and Laboratory Science,* 6(1):38–46, 1976.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5550, to read as follows:

§ 866.5550 Immunoglobulin (light chain specific) immunological test system.

(a) *Identification.* An immunoglobulin (light chain specific) immunological test system is a device that consists of the reagents used to measure by immunochemical techniques both kappa and lambda types of light chain portions of immunoglobulin molecules in serum, body fluids, and tissues. In some disease states, an excess of light chains are produced by the antibody-forming cells. These free light chains, unassociated with gamma globulin molecules, can be found in a patient's body fluids and tissues. Measurement of the various amounts of the different types of light chains aids in the diagnosis of multiple myeloma (cancer of antibody-forming cells), lymphocytic neoplasms (cancer of lymphoid tissue), Waldenstrom's macroglobulinemia (increased production of large immunoglobulins), and connective tissue diseases such as rheumatoid arthritis or systemic lupus erythematosus.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading

of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-11875 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 866

[Docket No. 78N-2260]

Medical Devices; Classification of Lactic Dehydrogenase Immunological Test Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying lactic dehydrogenase immunological test systems into class I (general controls). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class I. the effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Srikrishna Vadlamudi, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of lactic dehydrogenase immunological test systems:

1. Identification: A lactic dehydrogenase immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the activity of the lactic dehydrogenase enzyme in serum. Increased levels of lactic dehydrogenase are found in a variety of conditions, including megaloblastic anemia (decrease in the number of mature red blood cells), myocardial infarction (heart disease), and some forms of leukemia (cancer of the blood-forming organs), However, the diagnostic usefulness of this device is limited because of the many conditions known to cause increased lactic dehydrogenase levels.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that lactic dehydrogenase immunological test systems be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that lactic dehydrogenase immunological test systems be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5560, to read as follows:

§ 866.5560 Lactic dehydrogenase immunological test system.

(a) *Identification.* A lactic dehydrogenase immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the activity of the lactic dehydrogenase enzyme in serum. Increased levels of lactic dehydrogenase are found in a variety of conditions, including megaloblastic anemia (decrease in the number of mature red blood cells), myocardial infarction (heart disease), and some forms of leukemia (cancer of the blood-forming organs). However, the diagnostic usefulness of this device is limited because of the many conditions known to cause increased lactic dehydrogenase levels.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-11876 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 866

[Docket No. 78N-2261]

Medical Devices; Classification of Lactoferrin Immunological Test Systems

AGENCY: Food and Drug Administation.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying lactoferrin immunological test systems into class I (general controls). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Srikrishna Vadlamudi, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of

Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classifiction Panel, an FDA advisory committee, made the following recommendation regarding the classification of lactoferrin immunological test systems:

1. Identification: A lactoferrin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the lactoferrin (an iron-binding protein with the ability to inhibit the growth of bacteria) in serum, human milk, body fluids, and tissues. Measurement of lactoferrin may aid in the diagnosis of an inherited deficiency of this protein.

2. Recommendation classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that the lactoferrin immunological test system be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based it recommendation on the Panel member's personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that lactoferrin immunological test systems be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5570, to read as follows:

§ 866.5570 Lactoferrin immunological test system.

(a) *Identification.* A lactoferrin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the lactoferrin (an iron-binding protein with the ability to inhibit the growth of bacteria) in serum, human milk, body fluids, and tissues. Measurement of lactoferrin may aid in the diagnosis of an inherited deficiency of this protein.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be indentified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11877 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2262]

Medical Devices; Classification of Alpha-1-Lipoprotein Immunological Test Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying alpha-1-lipoprotein immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of alpha-1-lipoprotein immunological test systems:

1. Identification: An alpha-1-lipoprotein immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the alpha-1-lipoprotein (high-density lipoprotein) in serum or plasma. Measurement of alpha-1-lipoprotein may aid in the diagnosis of Tangier disease (a hereditary disorder of fat metabolism).

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the alpha-1-lipoprotein immunological test system be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, stability, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Tangier disease is a genetic disorder consisting of a complete or nearly complete absence of plasma alpha-1-lipoprotein. Its predominant clinical features include hypocholesterolemia (low levels of cholesterol), increased levels of serum triglycerides (neutral fats synthesized from carbohydrates for storage in animal adipose cells), tonsils of unusual size and discoloration, and sometimes hepatosplenomegaly (enlarged liver and spleen). Kocen et al. (Ref. 1) has also reported a patient with neurological abnormalities. Alpha-1-lipoprotein can be measured immunochemically by immunoelectrophoresis. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, stability, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1 and 2).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of Tangier disease. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that alpha-1-lipoprotein immunological test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Kocen, R. S., J. K. Lloyd, P. T. Lascelles, A. S. Fosbrooke, and D. Williams, "Familial Alpha-lipoprotein Deficiency (Tangier Disease) with Neurological Abnormalities," *Lancet*, Vol. I:1341–1345, 1967.

2. Frederickson, D. S., "Inheritance of High Density Lipoprotein Deficiency (Tangier Disease)," *Journal of Clinical Investigation*, 43(2):228–236, 1964.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5580, to read as follows:

§ 866.5580 Alpha-1-lipoprotein immunological test system.

(a) *Identification.* An alpha-1-lipoprotein immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the alpha-1-lipoprotein (high-density lipoprotein) in serum of plasma. Measurement of alpha-1-lipoprotein may aid in the diagnosis of Tangier disease (a hereditary disorder of fat metabolism).

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11878 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2263]

Medical Devices; Classification of Lipoprotein X Immunological Test Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying lipoprotein X immunological test systems into class I (general controls). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of lipoprotein X immunological test systems:

1. Identification: A lipoprotein X immunological test system is a device that consists of the reagents used to measure by immunochemical techniques lipoprotein X (a high-density lipoprotein) in serum and other body fluids. Measurement of lipoprotein X aids in the diagnosis of obstructive liver disease.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that the lipoprotein X immunological test system be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that lipoprotein X immunological test systems be classified into class I (general controls) with no exemption. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5590, to read as follows:

§ 866.5590 Lipoprotein X immunological test system.

(a) *Identification.* A lipoprotein X immunological test system is a device that consists of the reagents used to measure by immunochemical techniques lipoprotein X (a high-density lipoprotein) in serum and other body fluids. Measurement of lipoprotein X aids in the diagnosis of obstructive liver disease.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be

submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-11879 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 866

[Docket No. 78N-2264]

Medical devices; Classification of Low-Density Lipoprotein Immunological Test Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying low-density lipoprotein immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Srikrishna Vadlamudi, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910 301-427-7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of low-density lipoprotein immunological test systems:

1. Identification: A low-density lipoprotein immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the low-density lipoprotein in serum and other body fluids. Measurement of low-density lipoprotein in serum may aid in the diagnosis of disorders of lipid (fat) metabolism and help to identify young persons at risk from cardiovascular diseases.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the low-density lipoprotein immunological test system be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, stability, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. These tests are useful in the evaluation of patients in whom cholesterol levels are being monitored. Low-density lipoproteins function to transport cholesterol and fatty acids. Low-density lipoprotein measurement is an effective means of identifying patients, particularly the young, who may be at high risk of cardiovascular disease. Disorders of lipid (fat) metabolism in body tissues may also be detected by this device (Refs. 1 through 3). The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, stability, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with the device and upon a review of the literature (Refs. 1, 2, and 3).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of disorders of fat metabolism or of heart disease in young persons. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that low-density lipoprotein immunological test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Fredrickson, D. S., R. I. Levy, and R. S. Lees, "Fat Transport in Lipoproteins—an Integrated Approach to Mechanisms and Disorders," *New England Journal of Medicine,* 276:34-44, 94-103, 148-156, 215-225, 273-281, 1967.

2. Fisher, W. R., and D. H. Truitt, "The Common Hyperlipoproteinemias. An Understanding of Disease Mechanisms and Their Control," *Annals of Internal Medicine,* 85:497-508, 1976.

3. Fredrickson, D. S. and R. S. Lees, "A System for Phenotyping Hyperlipoproteinemia," *Circulation,* 31:321-327, 1965.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5600, to read as follows:

§ 866.5600 Low-density lipoprotein immunological test system.

(a) *Identification.*—A low-density lipoprotein immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the low-density lipoprotein in serum and other body fluids. Measurement of low-density lipoprotein in serum may aid in the diagnosis of disorders of lipid (fat) metabolism and help to identify young persons at risk from cardiovascular diseases.

(b) *Classification.*—Class II (performance standards).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading

of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-11880 Filed 4-21-80 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 866

[Docket No. 78N-2265]

Medical Devices; Classification of Alpha-2-macroglobulin Immunological Test Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed Rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying alpha-2-macroglobulin immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Srikrishna Vadlamudi, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of alpha-2-macroglobulin immunological test systems:

1. Identification: An alpha-2-macroglobulin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the alpha-2-macroglobulin (a serum protein) in plasma. Measurement of alpha-2-macroglobulin may aid in the diagnosis of blood clotting or clot lysis disorders.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that alpha-2-macroglobulin immunological test systems be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, stability, precision, sensitivity and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Alpha-2-macroglobulin is a normally occurring glycoprotein (carbohydrate-containing protein) in the plasma of humans. Studies indicate one of the functions of the functions of alpha-2-macroglobulin may be binding and removal of proteolytic enzymes from the body (Ref. 1). The Panel assumes that alpha-2-macroglobulin functions in the body as protection against autodigestion (Ref. 1). However, Steins and Mehl (Ref. 2) believe alpha-2-macroglobulin's physiologic role is related more to blood clotting or clot lysis than to any interaction with proteolytic enzymes. the levels of alpha-2-macroglobulin do not increase during the infection (Ref. 3), nor do they increase in systemic sclerosis (wasting of nerve cells) (Ref. 4). In contrast, alpha-2-macroglobulin concentration increases in chronic progressive polyarthritis (rheumatism) (Ref. 1), diabetes mellitus, and in patients with kidney disease (Ref. 2). Van Oss, et al., (Ref. 5) report that immunochemical tests may detect alpha-2-macroglobulin in urine of patients suffering from kidney disease. In reality, physical and chemical tests show only smaller fragments of the proteins present in the urine. It may be assumed that proteins undergo enzymatic breakdown as they pass from the kidney into the urine. Immunochemical methods cannot discriminate between a given protein and its subunits (breakdown).

Subunits of various serum proteins can occur under normal and pathological conditions. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, stability and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, these devices and upon a review of the literature (Refs. 1 through 5).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of various disorders, including blood disorders, kidney disease, and chronic rheumatism. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that alpha-2-macroglobulin immunological test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for the device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Jakab, L., T. Pozsonsyi, and J. Feher, "Serum Glycoproteins in Autoimmune Diseases, *Acta Medica Academiae Scientiarum Hungaricae, Tomus,* 33(2):161-169, 1976.

2. Steines, W. J. and J. W. Mehl, "The Elevation of Alpha-2-macroglobulin and Trypsin-binding Activity in Nephrosis," *Journal of Laboratory and Clinical Medicine* 67(4):559-565, 1966.

3. Schelp, F. P., P. Migasena, P. Pongpaew, W. H. P. Schreurs, and V. Supawan, "Serum Proteinase Inhibitors and Other Serum Proteins in Protein-Energy Malnutrition," *British Journal of Nutrition* 38:31-39, 1977.

4. Husson, J. M., A. LeGo, R. Engler, M. P. Ollier, J. N. Fiessinger, E. Housset, and L. Hartman, "Immunochemical Study on Serum Proteins in Systemic Sclerosis," *Biomedicine* 26:182-187, 1977.

5. Van Oss, C. J., M. K. Hawking, and P. M. Bronson, "A Comparison Between Immunochemical and Physical Chemical Analyses of the Molelcular Size of Urinary Proteins," *Biochemical Medicine* 7:466-472, 1973.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5620, to read as follows:

§ 866.5620 Alpah-2-macroglobulin immunological test system.

(a) *Identification.* An alpha-2-macroglobulin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the alpha-2-macroglobulin (a serum protein) in plasma. Measurement of alpha-2-macroglobulin may aid in the diagnosis of blood-clotting or clot lysis disorders.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the hearing of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11881 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2266]

Medical Devices; Classification of Beta–2–Microglobulin Immunological Test Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying beta–2–microglobulin immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of beta–2–microglobulin immunological test systems:

1. Identification: A beta–2–microglobulin immunological test system is device that consists of the reagents used to measure by immunochemical techniques the beta–2–microglobulin (a protein molecule) in serum, urine, and other body fluids. Measurement of beta–2–microglobulin aids in the diagnosis of patients with active rheumatoid arthritis and kidney disease.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the beta–2–microglobulin immunological test system be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, stability, precision, sensitivity and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily.

Beta–2–microglobulin is a small molecular weight serum protein and is associated with human cell surface antigens. It is present in low concentrations in normal serum, urine, spinal fluid, colostrum (human milk protein), and amniotic fluid. Serum levels have been shown to increase with age, and levels are consistently higher in females than in males. They are also increased in synovial (joint) fluid of patients with active rheumatoid arthritis and in saliva of patients with Sjogren's syndrome (a type of disease of the cornea of the eye) (Ref. 1). It appears that beta–2–microglobulin is eliminated by the kidney, and levels may be used to monitor renal tubular deficiency. Teasdale et al. (Ref. 2) have concluded that serum levels of beta–2–microglobulin are increased in cancer patients, but note that the biological significance of these findings is subject to debate.

The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, stability, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1 and 2).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of rheumatoid arthritis, Sjogrens syndrome, and kidney disorders. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that beta-2-microglobulin immunological test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Fye, K., H. Moutsopoulos, and N. Talal, "Rheumatoid Diseases," *in* "Basic and Clinical Immunology," Edited by Fudenberg, H. H., D. P. Stites, J. L. Caldwell, and J. V. Wells, Lange Medical Publications, Los Altos, p. 374, 1976.

2. Teasdale, C., A. M. Mander, R. Fifield, J. W. Keyser, R. G. Newcombe, and L. E. Hughes, "Serum beta-2-Microglobulin in Controls and Cancer Patients," *Clinica Chimica Acta* 78: 135–143, 1977.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5630, to read as follows:

§ 866.5630 Beta-2-microglobulin immunological test system.

(a) *Identification.* A beta-2-microglobulin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques beta-2-microglobulin (a protein molecule) in serum, urine, and other body fluids. Measurement of beta-2-microglobulin aids in the diagnosis of patients with active rheumatoid arthritis and kidney disease.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11882 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2267]

Medical Devices; Classification of infectious Mononucleosis Immunological Test Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying infectious mononucleosis immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Siver spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. the Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of infectious mononucleosis immunological test systems:

1. Identification: An infectious mononucleosis immunological test system is a device that consists of the reagents used to measure by immunochemical techniques infectious mononucleosis antibodies in serum, plasma, and body fluids. Measurments of infectious mononucleosis antibodies aid in the diagnosis of infectious mononucleosis.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that the infectious mononucleosis immunological test system be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, stability, precision, sensitivity, and specifity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Infectious mononucleosis is an acute and self-limiting disease occurring most frequently in the young adult. The Epstein-Barr virus, which is responsible for the disease, is most often detected indirectly with various immunochemical techniques. Between 50 and 90 percent of patients with infectious mononucleosis develop heterophile antibodies (antibodies which will cause the red blood cells of several different animals, e.g., sheep, horse, and cow, to agglutinate or clump together). The agglutination of sheep or horse red cells is the common method used for the detection of this heterophilic infectious nononucleosis antibody. Heterophile antibodies may also appear during serum sickness (an allergic reaction following a large injection of foreign serum), or they may be present in normal individuals. Positive identification of the heterophile antibodies of infectious mononucleosis can be made by a differential adsorption of the patient's serum with beef red cells and guinea pig kidney before testing for agglutination of sheep or horse red blood cells. Antibodies of infectious mononucleosis are adsorbed by beef red cells, but not by guinea pig kidney; serum sickness agglutinins are adsorbed by both; and normal serum heterophile antibodies are adsorbed by guinea pig kidney, but not usually by beef red blood cells. It is important to diagnose infectious mononucleosis correctly because the symptoms, particularly fever and enlargement of the lymph glands, are very similar to those of lymphatic and monocytic leukemia. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, stability and specificity. the Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: the Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1 through 3).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of infectious mononucleosis. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that infectious mononucleosis immunological test systems be classified into II (performance standards). The agency believes that a performance is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Gerber, P., J. Whang-Peng, and J. H. Monroe, "Transformation and Chromosome Changes Induced by Epstein-Barr Virus in Normal Human Leukocyte Cultures," Proceedings of National Academy of Science, U.S.A., 63: 740–747, 1969.

2. Paul, J. R. and W. W. Bunnell "The Presence of Heterophile Antibodies *in*

Infectious Mononucleosis," *The American Journal of Medical Science,* 183:90–104, 1932.

3. Lee, C. L., I. Davidsohn and R. Slaby, "Horse Agglutinins in Infectious Mononucleosis," *The American Journel of Clinical Pathology,* 49:3–11, 1968.

Therefore. under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371 (a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5640, to read as follows:

§ 866.5640 Infectious mononucleosis immunoligical test system.

(a) *Identification.* An infectious mononucleosis immunological test system is a device that consists of the reagents used to measure by immunochemical techniques infectious mononucleosis antibodies in serum, plasma, and body fluids. Measurements of infectious mononucleosis antibodies aid in the diagnosis of infectious monoucleosis.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11883 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2268]

Medical Devices; Classification of Multiple Autoantibodies Immunological Test Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying multiple autoantibodies immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of multiple autoantibodies immunological test systems:

1. Identification: A multiple autoantibodies immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the autoantibodies (antibodies produced against the body's own tissues) in human serum and other biological fluids. Measurement of multiple autoantibodies aids in the diagnosis of autoimmune disorders (diseases produced when the body's own tissues are injured by autoantibodies).

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that the multiple autoantibodies immunological test system be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, stability, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The device aids in the evaluation of patients in whom systemic lupus erythematosus (a multisystem autoimmune disease) or one of several other autoimmune connective tissue diseases produce a spectrum of autoantibodies (antibodies produced against patient's own tissues) against a variety of tissues. These multiple antibodies are not specific and will react with the antigenic components of cells from many species. Multiple autoantibodies may belong to any of the immunoglobulin classes (IgA, IgD, IgE, IgG, and IgM). Immunological procedures that have been used to detect multiple autoantibodies include: complement fixation, passive hemagglutination, passive agglutination, gel diffusion, counter immunoelectrophoresis, radioimmunoassays, and immunofluorescence assays. A significant number of apparently normal individuals also demonstrate autoantibodies in their serum. Consequently, for the definite diagnosis of a given autoimmune disorder, additional immunological tests are needed to interpret the significance of detecting multiple antoantibodies in serum. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, stability, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which The recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1 through 5).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of autoimmune disorders. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that multiple autoantibodies immunological test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Moake, J. L. and D. R. Schultz, "Hemolytic Anemia Associated with Multiple Autoantibodies and Low Serum Complement," *American Journal of Medicine,* 58(3) :431–437, 1975.

2. Notman, D. D., N. Kurata, and E. M. Tan, "Profiles of Antinuclear Antibodies in Systemic Rheumatic Disease," *Annals of Internal Medicine,* 83:464–469, 1975.

3. Shaller, J., C. Kupfer and R. J. Wedgwood, "Iridocyclitis in Juvenile Rheumatoid Arthritis," *Pediatrics,* 44:92–100, 1969.

4. Tan, E. M. and H. G. Kunkel, "Characteristics of a Soluble Nuclear Antigen Precipitating with Sera of Patients with Systemic Lupus Erythematosus," *Journal of Immunology,* 96:464–471, 1966.

5. Sharp, G. C., W. S. Irvin, R. L. LaRogue, C. Velez, V. Daly, A. D. Kaiser and H. R. Holman, "Association of Autoantibodies to Different Nuclear Antigens with Clinical Patterns of Rheumatic Disease and Responsiveness to Therapy," *The Journal of Clinical Investigation,* 50:350–359, 1971.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5660, to read as follows:

§ 866.5660 Multiple autoantibodies immunological test system.

(a) *Identification.* A multiple autoantibodies immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the autoantibodies (antibodies produced against the body's own tissues) in human serum and other biological fluids. Measurement of multiple autoantibodies aids in the diagnosis of autoimmune disorders (diseases produced when the body's own tissues are injured by autoantibodies).

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11884 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2269]

Medical Devices; Classification of Myoglobin Immunological Test Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying myoglobin immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comment to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of myoglobin immunological test systems:

1. Identification: A myoglobin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the myoglobin (an oxygen storage protein found in muscle) in serum and other body fluids. Measurement of myoglobin aids in the rapid diagnosis of patients with renal or heart disease.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that the myoglobin immunological test system be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, this device.

5. Risks to health: None identified.

Proposed Classification

FDA disagrees with the Panel recommendation that this device be classified into class I (general controls) and is proposing that myoglobin immunological test systems be classified into class II (performance standards). The agency has reviewed the Panel recommendation and has sought other information and data describing the measurement of myoglobin in patients suffering from heart attacks. Myoglobin is a protein synthesized by cardiac and skeletal muscle tissue. The snythesis of myoglobin and resulting myoglobinemia (myoglobin protein in urine) has been found to correlate with myocardial infarction (heart attact), skeletal muscle damage, circulatory collapse, and severe renal disease (Refs. 1 through 5). The agency notes that reliance on the diagnostic information derived from use of this device, if inaccurate, could result in a situation that may be hazardous to the patient's health. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the device's accuracy, precision, sensitivity, stability, and specificity. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Miyoshi, K., S. Saito, H. Kawai, A. Kondo, M. Iwasa, T. Hayashi, and M. Yagita, "Radioimmunoassay for Human Myoglobin: Methods and Results in Patients with Skeletal Muscle or Myocardial Disorders," *"Journal Laboratory and Clinical Medicine,* 92(3):341–352, Sept. 1978.

2. Reichlin, M., J. P. Visco, F. J. Klocke, "Radioimmunoassay for Human Myoglobin. Initial Experience in Patients with Coronary Heart Disease," *Circulation,* 57(1):52–56, Jan. 1978.

3. Stone, M. J., M. R. Waterman, D. Harimoto, G. Murray, N. Willson, M. R. Platt, G. Blomqvist, J. T. Willerson, "Serum Myoglobin Level as Diagnostic Test in Patients with Acute Myocardial Infarction, *"British Heart Journal,* 39(4):375–380, Apr. 1977.

4. Kagen, L., S. Scheidt, A. Butt, "Serum Myoglobin in Myocardial Infarction: the Staccato Phenomenon: Is acute Myocardial Infarction in Man and Intermittent Event?" *The American Journal of Medicine,* 62(1):86–92, Jan. 1977.

5. Donald, T. G., M. J. Cloonan, C. Neale, D. E. L. Wilcken, "Excretion of Myoglobin in Urine after Acute Myocardial Infarction, *"British Heart Journal,* 39(1):29–34, Jan. 1977.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5680, to read as follows:

§ 866.5680 Myoglobin immunological test system.

(a) *Identification.* A myoglobin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the myoglobin (an oxygen storage protein found in muscle) in serum and other body fluids. Measurement of myoglobin aids in the rapid diagnosis of patients with renal or heart disease.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11885 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2270]

Medical Devices; Classification of Whole Human Plasma or Serum Immunological Test Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying whole human plasma or serum immunological test systems into class I (general controls). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of whole human plasma or serum immunological test systems:

1. Identification: A whole human plasma or serum immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the proteins in human plasma or serum. Measurements of proteins in human plasma or serum aid in the diagnosis of any disease concerned with abnormal levels of plasma or serum proteins, e.g., agammaglobulinemia, allergies, multiple myeloma, rheumatoid vasculitis, or hereditary angioneurotic edema.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that the whole human plasma or serum immunological test system be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. A summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device. The immunochemical techniques that have been used include gel diffusion, immunoelectrophoresis, crossed-immunoelectrophoresis, counterimmunoelectrophoresis, radioimmunoassays or immunofluorescence assays.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that whole human plasma or serum immunological test systems be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5700, to read as follows:

§ 866.5700 Whole human plasma or serum immunological test system.

(a) *Identification.* A whole human plasma or serum immunological test system is a device that consists of reagents used to measure by immunochemical techniques the proteins in human serum or plasma. Measurements of proteins in human plasma or serum aid in the diagnosis of any disease concerned with abnormal levels of plasma or serum proteins, e.g., agammaglobulinemia, allergies, multiple myeloma, rheumatoid vasculitis, or hereditary angioneurotic edema.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980 submit to the Hearing

Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11886 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2271]

Medical Devices; Classification of Plasminogen Immunological Test Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying plasminogen immunological test systems into class I (general controls). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class I. The effect of classifying a defice into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of plasminogen immunological test systems:

1. Identification: A plasminogen immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the plasminogen (an inactive substance from which plasmin, a blood-clotting factor, is formed) in serum, body fluids, and tissues. Measurement of plasminogen levels may aid in the diagnosis of fibrinolytic (blood-clotting) disorders.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that the plasminogen immunological test system be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that plasminogen immunological test systems be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5715, to read as follows:

§ 866.5715 Plasminogen immunological test system.

(a) *Identification.* A plasminogen immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the plasminogen (an inactive substance from which plasmin, a blood-clotting factor, is formed) in serum, body fluids, and tissues. Measurement of plasminogen levels may aid in the diagnosis of fibrinolytic (blood-clotting) disorders.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11887 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2272]

Medical Devices; Classification of Prothrombin Immunological Test Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying prothrombin immunological test systems into class I (general controls). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of prothrombin immunological test systems:

1. Identification: A prothrombin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the prothrombin (clotting factor II) in serum. Measurements of the amount of antigenically competent (ability to react with protein antibodies) prothrombin aid in the diagnosis of patients with blood-clotting disorders.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that the prothrombin immunological test system be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of this device.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with a the Panel recommendation and is proposing that prothrombin immunological test systems be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5735, to read as follows:

§ 866.5735 Prothrombin immunological test system.

(a) *Identification.* A prothrombin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the prothrombin (clotting factor II) in serum. Measurements of the amount of antigenically competent (ability to react with protein antibodies) prothrombin aid in the diagnosis of patients with bloodclotting disorder.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11888 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2273]

Medical Devices; Classification of Radioallergosorbent (Rast) Immunological Test Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying radioallergosorbent (RAST) immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that 78–1873 the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of radioallergosorbent (RAST) immunological test systems:

1. Identification: A radioallergosorbent immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the allergen antibodies (antibodites which cause an allergic reaction) specific for a given allergen. Measurement of specific allergen antibodies may aid in the diagnosis of asthma, allergies, and other pulmonary disorders.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that the radioallergosorbent (RAST) immunological test system be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, stability, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The radioallergosorbent tests (RAST) were developed to detect the antibodies (IgE class) specific for particular organic dust allergens (Ref. 1). These tests are useful in the diagnosis of patients in whom an immediate allergic reaction to more than one organic dust allergen results in bronchial asthma symptoms. Antibodies may be directed against organic dusts derived from plant, fungal, or animal protein sources.

However, clinical allergy is caused by IgE-allergen complexes located in the tissues rather than circulating in body fluids. Both radioallergoabsorbent tests and passive tranfer tests only indicate the presence or absence of the particular IgE antibody in serum. A provocative test (a test which acutally provokes the allergic tissues with an allergen) is the most reliable method for determining the causative agent of an allergy. Pulmonary provocation tests are easy to perform and interpret, but many other provocation tests for other types of allergies are more demanding with regard to both equipment and experience.

In one study, the use of the radioallegosorbent test as a supplement to a carefully collected case history and critically evaluated skin tests made the performance of provocative tests superfluous in 82 percent of patients studied (Ref. 1). The Panel believes

that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, stability, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literaute (Refs. 1 through 3).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the identification of the causative agent in asthma, allergies, and other pulmonary disorders. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that radioallergosorbent (RAST) immunological test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Aas, K. and S. G. O. Johansson, "The Radioallergosorbent Test in the In Vitro Diagnosis of Multiple Reaginic Allergy," *Journal of Allergy and Clinical Immunology,* 48:134–142, 1971.

2. Wide, L., H. Bennich, and S. G. O. Johansson, "Diagnosis of Allergy by an In Vitro Test for Allergen Antibodies," *Lancet,* 2:1105–1107, 1967.

3. Gleich, G. J. and R. T. Jones "Measurement of IgE Antibodies by the Radioallergosorbent Test. I. Technical Considerations in the Performance of the Test," *Journal of Allergy and Clinical Immunology, 55:334–345, 1975.*

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5750, to read as follows:

§ 866.5750 Radioallergosorbent (RAST) immunological test system.

(a) *Identification.* A radioallergosorbent immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the allergen antibodies (antibodies which cause an allergic reaction) specific for a given allergen. Measurement of specific allergen antibodies may aid in the diagnosis of asthma, allergies, and other pulmonary disorders.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11889 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2274]

Medical Devices; Classification of Retinol-Binding Protein Immunological Test Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying retinol-binding protein immunological test systems into class I (general controls). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of retinol-binding protein immunological test systems:

1. Identification: A retinol-binding protein immunological test system is a device that consists of the reagents used to measure by immunochemical techniques retinol-binding protein that binds and transports vitamin A in serum and urine. Measurement of this protein may aid in the diagnosis of kidney disease and in monitoring patients with kidney transplants.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that the retinol-binding protein immunological test system be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that retinol-binding protein immunological test systems be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs

proposes to amend Part 866 in Subpart F by adding new § 866.5765, to read as follows:

§ 866.5765 Retinol-binding protein immunological test system.

(a) *Identification.* A retinol-binding protein immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the retinol-binding protein that binds and transports vitamin A in serum and urine. Measurement of this protein may aid in the diagnosis of kidney disease and in monitoring patients with kidney transplants.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11890 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2275]

Medical Devices; Classification of Rheumatoid Factor Immunological Test Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying rheumatoid factor immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immuology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of rheumatoid factor immunological test systems:

1. Identification: A rheumatoid factor immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the rheumatoid factor (antibodies to immunoglobulins) in human serum, body fluids, and tissues. Measurement of rheumatoid factor may aid in the diagnosis of rheumatoid arthritis.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that the rheumatoid factor immunological test system be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, stability, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Measurements of rheumatoid factor aid in the diagnosis of rheumatoid arthritis and other chronic inflammatory diseases, such as tuberculosis and leprosy. Rheumatoid factor present in patients with vasculitis (inflammation of veins) and rashes, particularly when limited to the legs, may be indicative of cancer of the lymphoid system. Immunochemical test procedures which have been used to detect rheumatoid factor antibodies include slide latex agglutination, latex tube dilution, and aggregated precipitin tests. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, stability, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1 through 6).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of rheumatoid arthritis. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that rheumatoid factor immunological test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The agency believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Allen, J. C. and H. G. Kunkel, "Hidden Rheumatoid Factors with Specificity for Native Gammaglobulins," *Arthritis and Rheumatism,* 9:758–768, 1966.

2. Edelman, G. M., H. G. Kinkel, and E. C. Franklin, "Interaction of the Rheumatoid Factor with Antigen Antibody Complexes and Aggregated Gammaglobulin," *Journal of Experimental Medicine,* 108:105–120, 1958.

3. Singer, J. M. and C. M. Plotz, "The Latex-Fixation Test-I Application to the Serologic Diagnosis of Rheumatoid Arthritis," *American Journal of Medicine,* 21:888–892, 1956.

4. Waller, M. V. and J. H. Vaughan, "Use of Anti-Rh Sera for Demonstrating Agglutination Activating Factor in Rheumatoid Arthritis," *Proceedings of the Society of Expermental Biology and Medicine,* 92:198–200, 1956.

5. Ziff, M., "The Agglutination Reaction in Rheumatoid Arthritis," *Journal of Chronic Disease,* 5:644–667, 1957.

6. Winchester, R., *Tests for Detection of the Rheumatoid Factors," in* "Manual of Clinical Immunology," edited by Noel R. Rose and Herman Friedman, American Society for Microbiology, Washington, DC, pp. 665–675, 1976.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513,

701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5775, to read as follows:

§ 866.5775 Rheumatoid factor immunological test system.

(a) *Identification.* A rheumatoid factor immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the rheumatoid factor (antibodies to immunoglobulins) in human serum, body fluids, and tissues. Measurement of rheumatoid factor may aid in the diagnosis of rheumatoid arthritis.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11891 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2276]

Medical Devices; Classification of Seminal Fluid (Sperm) Immunological Test Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying seminal fluid (sperm) immunological test systems into class I (general controls). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. the Immunology Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of seminal fluid (sperm) immunological test systems:

1. Identification: A seminal fluid (sperm) immunological test system is a device that consists of the reagents used for legal purposes to identify and differentiate animal and human semen. The test results can be used as court evidence in alleged instances of rape and other sex-related crimes.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that the seminal fluid (sperm) immunological test system be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that seminal fluid (sperm) immunological test systems be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5800, to read as follows:

§ 866.5800 Seminal fluid (sperm) immunological test system.

(a) *Identification.* A seminal fluid (sperm) immunological test system is a device that consists of the reagents used for legal purposes to identify and differentiate animal and human semen. The test results can be used as court evidence in alleged instances of rape and other sex-related crimes.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11892 Filed 4–27–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2277]

Medical Devices; Classification of Systemic Lupus Erythematosus Immunological Test Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying systemic lupus erythematosus immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These

actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of systemic lupus erythematosus immunological test systems:

1. Identification: A systemic lupus erythematosus (SLE) immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the autoimmune antibodies in serum and body fluids that react with cellular nuclear double-stranded deoxyribonucleic acid (DNA) or other nuclear constituents that are specifically diagnostic of SLE. Measurement of nuclear double-stranded DNA antibodies aids in the diagnosis of systemic lupus erythematosus (a multisystem autoimmune disease in which tissues are attacked by the person's own antibodies).

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that the systemic lupus erythematosus immunological test system be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, stability, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily.

Antibodies directed against certain defined nuclear antigens are more specific for SLE than for other connective tissue disorders. High titers of antibodies that react with double-stranded deoxyribonucleic acid (DNA) appear mainly in active SLE, although they have been found occasionally in patients with other diseases such as rheumatoid arthritis, juvenile rheumatoid arthritis, and chronic active hepatitis. The increase or decrease in the amount of antidouble-stranded DNA antibodies usually reflect disease activity or remission, respectively, and thus may be used to monitor SLE disease activity. Immunological test systems used to detect these antibodies may include gel diffusion, complement fixation, passive hemagglutination, latex or bentonite agglutination, counter immunoelectrophoresis, or radioimmunodiffusion.

An anti-Sm antibody (an antibody reacting with an acidic glycoprotein found in the cellular nucleus) is also highly specific for SLE, but is found in only about 20 percent of SLE patients.

The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, stability, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature. (Refs. 1 through 4).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of systemic lupus erythematosus. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that SLE immunological test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The agency believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Casals, S. P., G. J. Friou, and P. O. Teague, "Specific Nuclear Reaction Pattern of Antibody to DNA in Lupus Erythematosus Sera," *Journal of Laboratory and Clinical Medicine,* 62:625–631, 1963.

2. Gonzalez, E. N. and N. F. Rothfield, "Immunoglobulin Class and Pattern of Nuclear Fluorescence in Systemic Lupus Erythematosus," *New England Journal of Medicine,* 274:1333–1338, 1966.

3. Rothfield, N. F. and B. D. Stollar, "The Relation of Immunoglobulin Class, Pattern of Anti-nuclear Antibody and Complement-fixing Antibodies to DNA in Sera From Patients with Systemic Lupus Erythematosus," *Journal of Clinical Investigation,* 46:1785–1794, 1967.

4. Chapman, J. C., "Lupus Erythematosus Latex Tests Compared with the Immunofluorescence Method for Antinuclear Factor," *American Journal of Medical Technology,* 42(5):126–129, 1976.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5820, to read as follows:

§ 866.5820 Systemic lupus erythematosus immunological test system.

(a) *Identification.* A systemic lupus erythematosus (SLE) immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the autoimmune antibodies in serum and body fluids that react with cellular nuclear double-stranded deoxyribonucleic acid (DNA) or other nuclear constituents that are specifically diagnostic of SLE. Measurement of nuclear double-stranded DNA antibodies aids in the diagnosis of systemic lupus erythematosus (a multisystem autoimmune disease in which tissues are attacked by the person's own antibodies).

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11893 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

21 CFR Part 866

[Docket No. 78N-2278]

Medical Devices; Classification of Total Spinal Fluid Immunological Test Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying total spinal fluid immunological test systems into class I (general controls). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FUTHER INFORMATION CONTACT: Srikrishna Vadlamudi, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7550.

SUPPLEMENTARY INFORMATION

Panel Recommendation

A proposal elswhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of total spinal fluid immunological test systems:

1. Identification: A total spinal fluid immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the total protein in cerebrospinal fluid. Measurement of spinal fluid proteins may aid in the diagnosis of inflamation of the central nervous system.

2. Recommended classification: Class I (general controls). the Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that the total spinal fluid immunological test system be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of date on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that total spinal fluid immunological test systems be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5860, to read as follows:

§ 866.5860 Total spinal fluid immunological test system.

(a) *Identification.* A total spinal fluid immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the total protein in cerebrospinal fluid. Measurement of spinal fluid proteins may aid in the diagnosis of inflammation of the central nervous system.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80-11894 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 866

[Docket No. 78N-2279]

Medical Devices; Classification of Thyroid Autoantibody Immunological Test Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying thyroid autoantibody immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

ADDRESS: Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Srikrishna Vadlamudi, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. the Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of thyroid autoantibody immunological test systems:

1. Identification: A thyroid autoantibody immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the autoantibodies (antibodies produced against the body's own tissues) to thyroid tissues. Measurement of thyroid autoantibodies may aid in the diagnosis of certain thyroid disorders, such as Hashimoto's disease (chronic lymphocytic thyroiditis), nontoxic

goiter (enlargement of thyroid gland), Grave's disease (enlargement of the thyroid gland with protrusion of the eyeballs), and cancer of the thyroid.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that the thyroid autoantibody immunological test system be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, stability, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Detection and measurement of thyroid antibodies aid in distinguishing Hashimoto's disease (chronic lymphocytic thyroiditis) from nontoxic goiter, Grave's disease, and several types of cancer of the thyroid. Immunochemical techniques used for the detection and measurement of thyroid autoantibodies include the following: sheep cell hemagglutination, latex agglutination, bentonite agglutination, complement fixation, immunofluorescence, and cytotoxicity assays. Low levels of thyroid autoantibodies have also been found in patients with pernicious anemia (reduced hemoglobin due to inability of the body to absorb vitamin B_{12}), atrophic gastritis (long-lasting inflammation of the stomach with atrophy of the mucous membrane and glands), and other disorders. About 80 percent of cases with thyrotoxicosis (a disease condition resulting from overactivity of the thyroid gland) also have increased thyroid autoantibody levels (Refs. 1 through 4). Because false-positive results are common with immunochemical techniques, diagnosis of Hashimoto's disease should be confirmed histologically by a needle biopsy. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, stability and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1 through 4).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an eror in the differentiation of chronic lymphocytic thyroiditis (Hashimoto's Disease) from nontoxic goiter (Grave's disease), and several types of cancer of the thyroid. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that thyroid autoantibody immunological test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The agency believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Amino, N., S. R. Hagen, N. Yamada and S. Refetoff, "Measurement of Circulating Thyroid Microsomal Antibodies by the Tanned Red Cell Haemagglutination Technique: Its Usefulness in the Diagnosis of Autoimmune Thyroid Diseases," *Clinical Endocrinology*, 5(2):115–125, 1976.

2. Pinchera, A., et al., "Studies on the Nature of Thyroid Antigens Involved in Thyroid Autoimmune Disorders," *in* "Thyroid Research," edited by J. Robbins et al., *Excerpta. Medica.*, Amsterdam, 1976. pp. 395–398.

3. Perrin, J. and M. A. bubel, "Assessment of a Haemagglutination Test for Thyroid Microsomal Antibody," *Medical Laboratory Technology*, 31(3):205–211, 1974.

4. Rose, N. R., "Endocrine Diseases" *in* "Basic and Clinical Immunology," edited by H. M. Fudenberg, D. P. Stites, J. L. Caldwell, and J. Vivian Wells, Lange Medical Publications, Los Altos, Calif. 554–563, 1976.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5870, to read as follows:

§ 866.5870 Thyroid autoantibody immunological test system.

(a) *Identification.* A thyroid autoantibody immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the autoantibodies (antibodies produced against the body's own tissues) to thyroid tissues. Measurement of thyroid autoantibodies may aid in the diagnosis of certain thryoid disorders, such as Hashimoto's disease (chronic lymphocytic thyroiditis), nontoxic goiter (enlargement of thryoid gland), Grave's disease (enlargement of the thyroid gland with protrusion of the eyeballs), and cancer of the thyroid.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11895 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2280]

Medical Devices; Classification of Transferrin Immunological Test Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying transferrin immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of transferrin immunological test systems:

1. Identification: A transferrin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the transferrin (an iron-binding and transporting serum protein) in serum, plasma, and body fluids. Measurement of transferrin levels aids in the diagnosis of malnutrition, acute inflammation, infection, and red blood cell disorders such as iron deficiency anemia.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that the transferrin immunological test system be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, stability, precision, sensitivity, and specifity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Transferrin is a glycoprotein (carbohydrate-containing protein) synthesized mainly in the liver. Transferrin functions in iron binding and transport and is the most important pathway by which iron gains access to the red blood cell-forming organs. Normally, most of the iron found in the circulatory system (blood and plasma) is bound to transferrin. The ratio of serum iron level to plasma transferrin level (percent saturation) varies from disease to disease. An increase in the saturation of transferrin can occur in conditions of decreased circulating protein (liver disease), blockage of hemoglobin synthesis, iron overload, and acute blood loss. A decrease in the saturation of transferrin is present in iron deficiency eenemia, malignant tumors, and late pregnancy. Measurement of transferrin levels also aids in evaluation of red blood cell disorders and infections.

The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, stability, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1–4).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of anemia, malnutrition, acute inflammation, and infection. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that the transferrin immunological test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency believes that there is sufficient information to establish a performance standard for this device.

References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Henry, J. B., "Clinical Diagnosis by Laboratory Methods," 15th Ed., W. B. Saunders Co., Philadelphia, pp. 652–656, 1975.

2. Ingenbleek, Y., H. van den Schrieck, P. de Nayer, and M. de. Visscher, "Albumin, Transferrin and the Thyroxine-Binding Prealbumin/Retinol-Binding Protein (TBPA–RBP) Complex in Assessment of Malnutrition" *Clinica Chimica Acta,* 63:61–67, 1975.

3. Tietz, N. W., "Fundamentals of Clinical Chemistry," 2d Ed., W. B. Saunders Co, Philadelphia, pp. 926–928, 1976.

4. Wintrobe, N. M. and G. R. Lee, "Iron Deficiency Anemia and other Hypochromic Microcytic Anemias," *in* "Harrison's Principles of Internal Medicine," 7th Ed., McGraw-Hill, New York, pp. 1581–1585, 1974.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5880, to read as follows:

§ 866.5880 Transferrin immunological test system.

(a) *Identification.* A transferrin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the transferrin (an iron-binding and transporting serum protein) in serum, plasma, and body fluids. Measurement of transferrin levels aids in the diagnosis of malnutrition, acute inflammation, infection, and red blood cell disorders such as iron deficiency anemia.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11896 Filed 4–27–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2281]

Medical Devices; Classification of Inter-Alpha Trypsin Inhibitor Immunological Test Systems

AGENCY: Food and Drug Administration.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying inter-alpha trypsin inhibitor immunological test systems into class I (general controls). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

ADDRESS: Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of

Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

SUPPLEMENTARY INFORMATION:

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of inter-alpha trypsin inhibitor immunological test systems:

1. Identification: An inter-alpha trypsin inhibitor immunological test system is a device that consists of the reagents used to measure by immuno-chemical techniques the inter-alpha trypsin inhibitor (a protein) in serum and body fluids. Measurement of inter-alpha trypsin inhibitor may aid in the diagnosis of acute bacterial infection and inflammation.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that inter-alpha trypsin inhibitor immunological test systems be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: None identified.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that inter-alpha trypsin inhibitor immunological test systems be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in subpart F by adding new § 866.5896, to read as follows:

§ 866.5890 Inter-alpha trypsin inhibitor immunological test system.

(a) *Identification.* An inter-alpha trypsin inhibitor immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the inter-alpha trypsin inhibitor (a protein) in serum and body fluids. Measurement of inter-alpha trypsin inhibitor may aid in the diagnosis of acute bacterial infection and inflammation.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–11897 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M